eIRB User Manual

Research Subjects Protections Office
Kaiser Permanente Northwest

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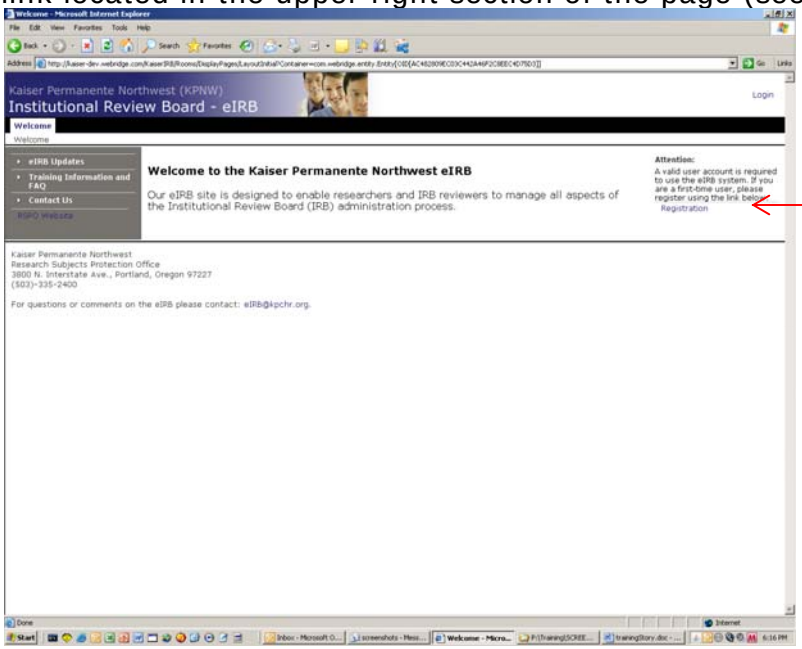
INTRODUCTION

The Electronic Institutional Review Board (eIRB), is a web-based application that provides tools for submitting and managing requests to the KPNW Institutional Review Board (IRB) for approval of human subjects research. The eIRB streamlines the process of submitting research studies to the IRB by eliminating the need for paper and by providing an easy way to process all study-related documentation electronically.

REGISTRATION

To register in the system, open your Internet browser. Go to https://eirb.kpchr.org. Click the 'Registration' link located in the upper right section of the page (see Figure 1).



You will register once.

Register by clicking here.

Figure 1

Next, fill out and submit the registration form (see Figure 2).

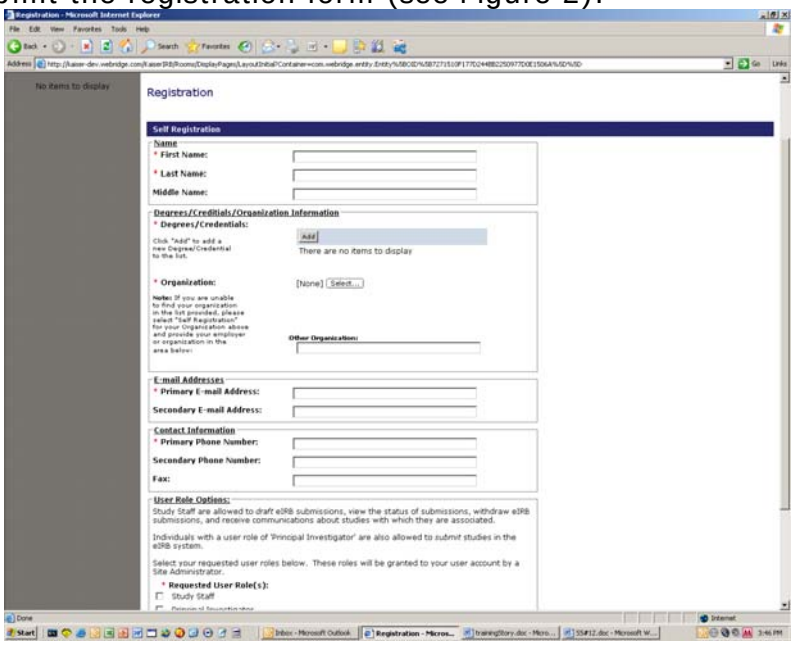


Figure 2

LOGGING INTO THE eIRB

You will receive an e-mail containing your username and temporary password, usually within two business days after submitting the registration form. You can use this username and temporary password to log into the eIRB. Go to http://eirb.kpchr.org, click on 'Login' located in the upper right section of the page, and enter your username and temporary password (see Figure 3).

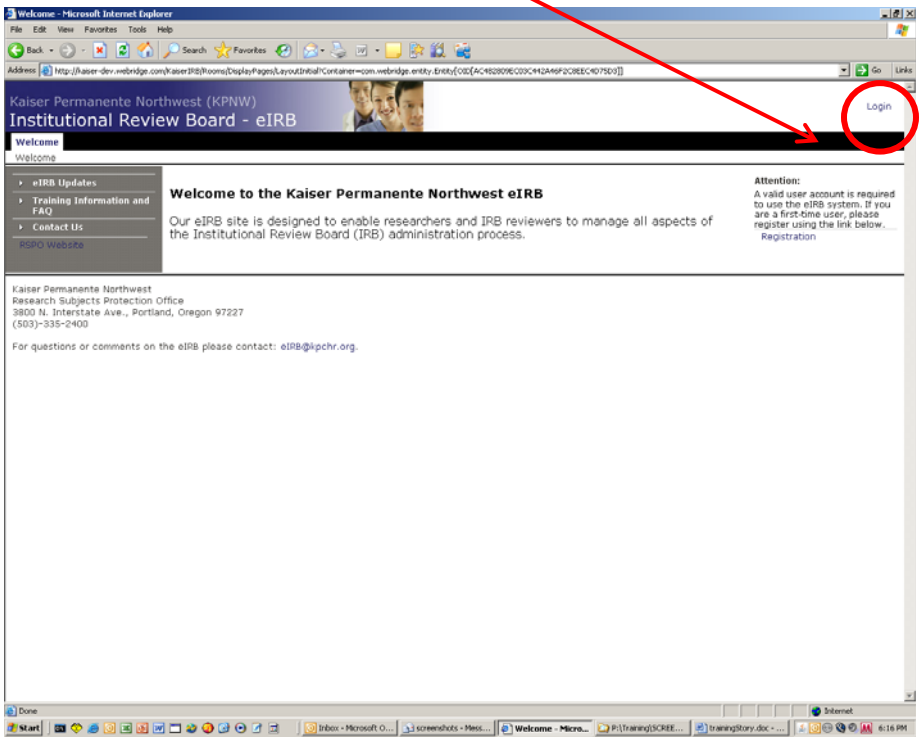


Figure 3

After clicking 'log-in', enter your username and password (see Figure 4 below). If this is your first time logging in, the eIRB will prompt you to change your password. This is necessary for security reasons. The new password is case sensitive and will need to be at least 8 characters and contain at least 1 number. Please safeguard your password. You should be the only person who has access to your eIRB account. Please note that willingly providing your username and password to anyone will constitute a violation of KPNW and CHR policies regarding the use of electronic resources. These policies can be found at the following links:

http://centernet/centernet/LeadershipPolicies/policies/COMP_ACC.html

http://npl.kp.org/pl/do/public/record?subcatid=5001&VIEW=M&rid=76142601&rgid=900

Disciplinary action —up to and including termination—may be taken against those who fail to adhere to this policy, per KPNW Principles of Responsibility:

http://kpnet.kp.org/national/compliance/principles/introduction_disciplinary.html

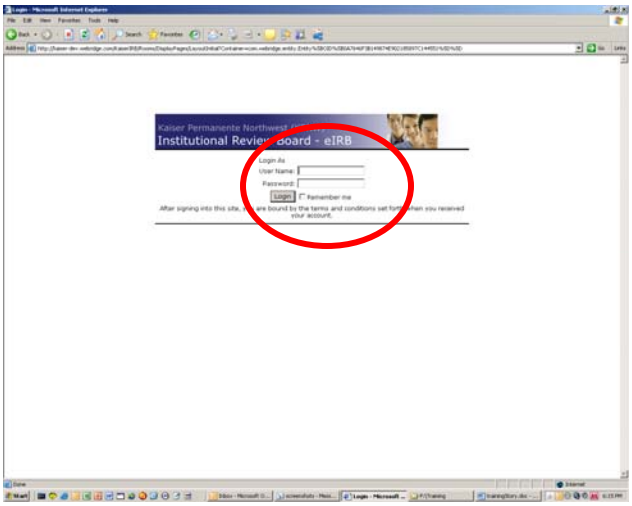


Figure 4

'My Home' Overview

The 'My Home' area of the eIRB is considered the starting point of the eIRB system. If you lose track of where you are in the eIRB, you can click on the link 'My Home' located in the upper right section of the eIRB system to return to this page (see Figure 5).

In the main area of the 'My Home' screen you will find a tab labeled 'Inbox' (see Figure 5), which contains the following submission header types: Study Protocols (IRQs/studies), Modifications, Continuing Reviews, and Reportable Events. If an item is listed below one of these headers when the 'inbox' tab is selected, some type of action is required from the investigator such as revising the submission as instructed by an IRB staff member, responding to contingencies, etc.

Next to the 'My Inbox' tab you will find tabs for the following submission types: Study Protocols (IRQs/studies), Modifications, Continuing Reviews, Reportable Events, Completed/withdrawn studies, and IRB inquiries (see Figure 6). Each tab contains the same type of submissions as described by its name. However, unlike those filtered under the 'My Inbox' tab, these tabs contain items that do not, generally, require your action to move them to the next state in the review process.

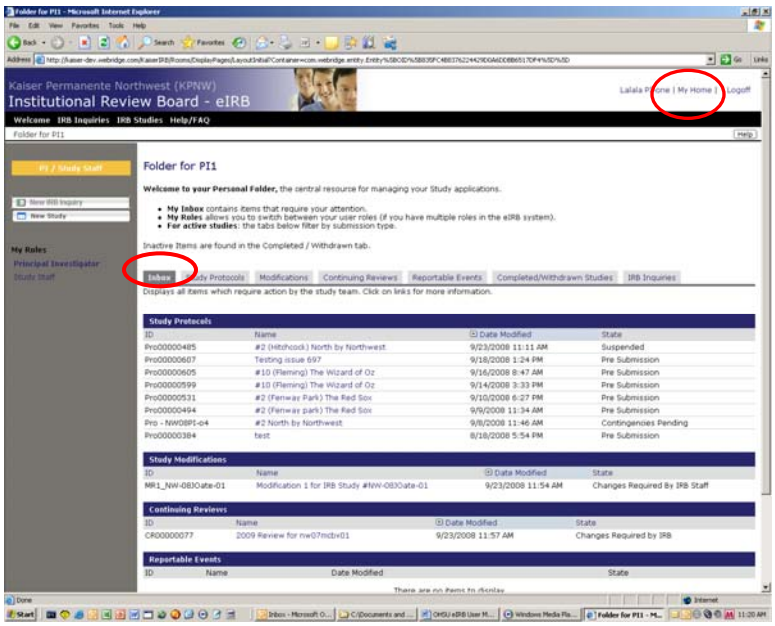


Figure 5

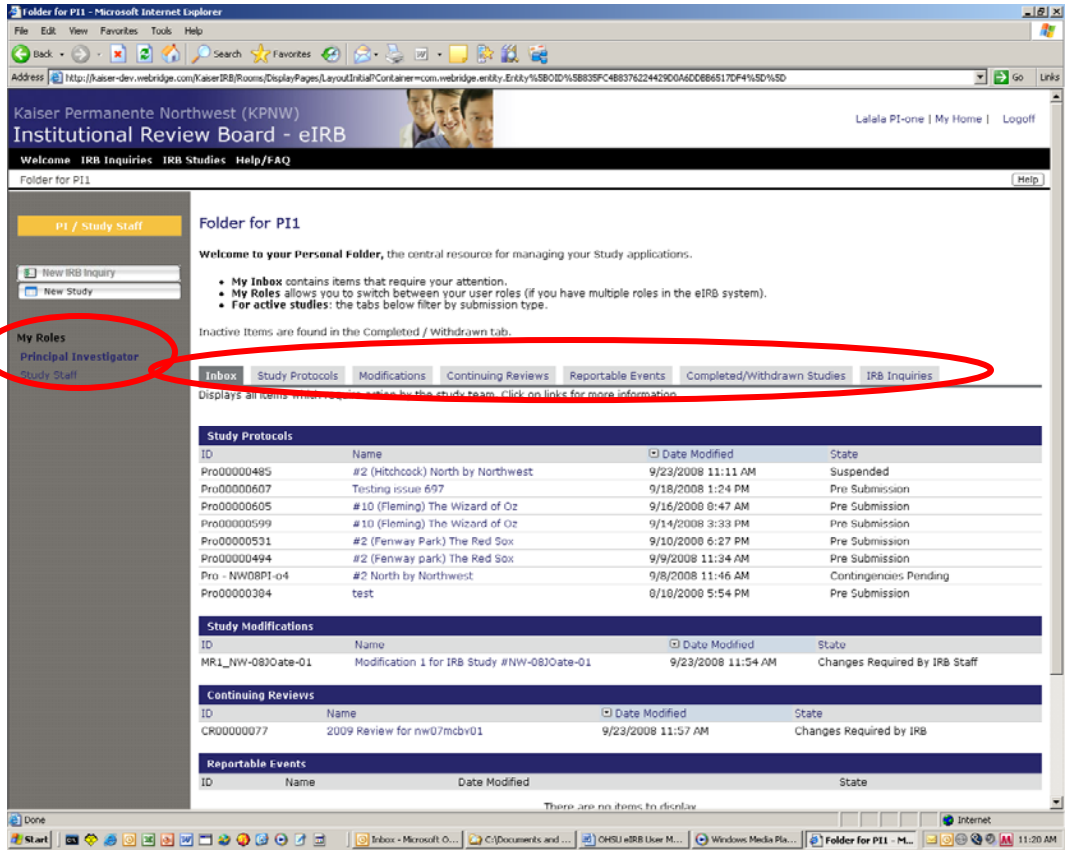


Figure 6

In the left hand section of the ''My Home'' area you will find 'My roles' (see above, Figure 6), which indicates your role(s) within the eIRB system. Most users will have one of the following:

- Study staff: If you draft/prepare submissions for an investigator but do not act as an investigator, this will be your role.

- Study staff and Principal Investigator (PI): If you draft/prepare submissions and act as an investigator ('Submit' studies on which you are the PI), this will be your role set.

- Study staff, Principal Investigator, and Mentor: If you draft/prepare submissions, act as an investigator ('Submit' studies on which you are the PI), and have the ability to act as a mentor to less experienced researchers, this will be your role set.

If you have multiple roles, click on/ use the role appropriate to your current purpose. The display for your inbox, for example, may differ depending on the role you are using.

Note: From your My Home page, you may click 'eIRB Information' to see a general, non-tailored eIRB page containing useful contact information for support personnel and materials related to the eIRB system (see below, Figure 7).

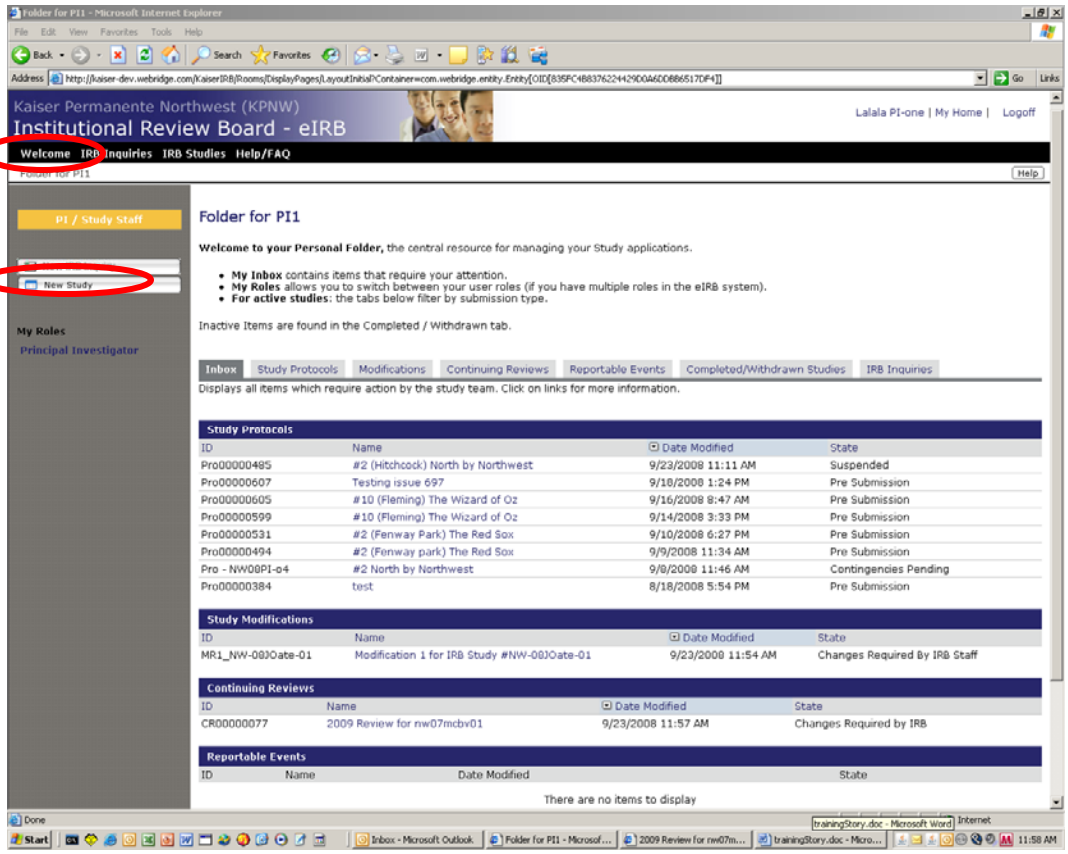


Figure 7

CREATING A NEW STUDY

From the 'My Home' environment, on the left hand side of the screen, you have the option to create a 'New Study' (see above, Figure 7). This button allows you to access the form through which you can: 1) Submit a request to the IRB to have a new study approved; 2) Convert an existing hardcopy study to the eIRB; or 3) Request that the KPNW IRB cede their review to another IRB for a *new* (not yet submitted) study.

- When you click this 'New Study' button the first page of the Initial Review Questionnaire (IRQ) appears (see Figure 8). Answer the applicable questions on the page. Required fields are indicted by a red asterisk.

- Once you have completed entering information into this first screen, click on the 'Continue' button located in the upper and the lower right portion of the page. Alternatively, if you wish to exit and not move beyond the first screen, click on the 'Save' link first, which is located in the upper middle portion of the page, and the eIRB system will automatically save your IRQ and create a new IRB number for your study. Once you click 'Save' you may click 'Exit' to exit the form.

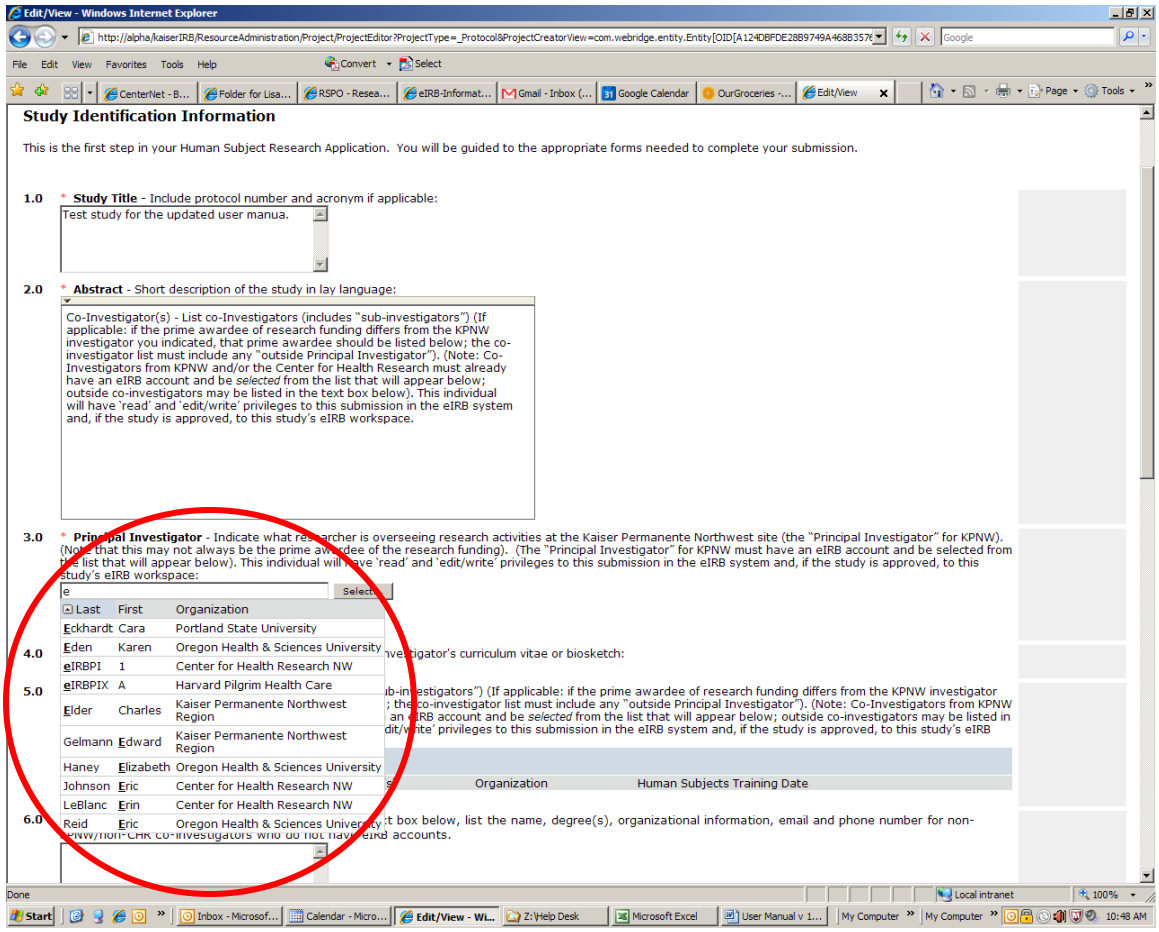


Figure 8

Adding Investigators and staff to the study submission

There are two ways to add study personnel to the IRQ. First, type the first few letters of the last name in the field and the system will auto populate from the system's registered users. You may also click the 'Select' button to add study personnel (see Figure 8). Once the 'Select' page has opened, in the 'Filter by' drop-down list box, select Last name, First name, or Organization, and enter the search criteria; for example, choose 'Last' name and then enter the first letter of the individual's last name. Click the 'Go' button and the name should appear in the results field. Then, select the checkbox next to the person you wish to add, and click 'OK' (see Figure 9).

You **must** add yourself as a Primary Contact or the system will not allow you to proceed to the next page.

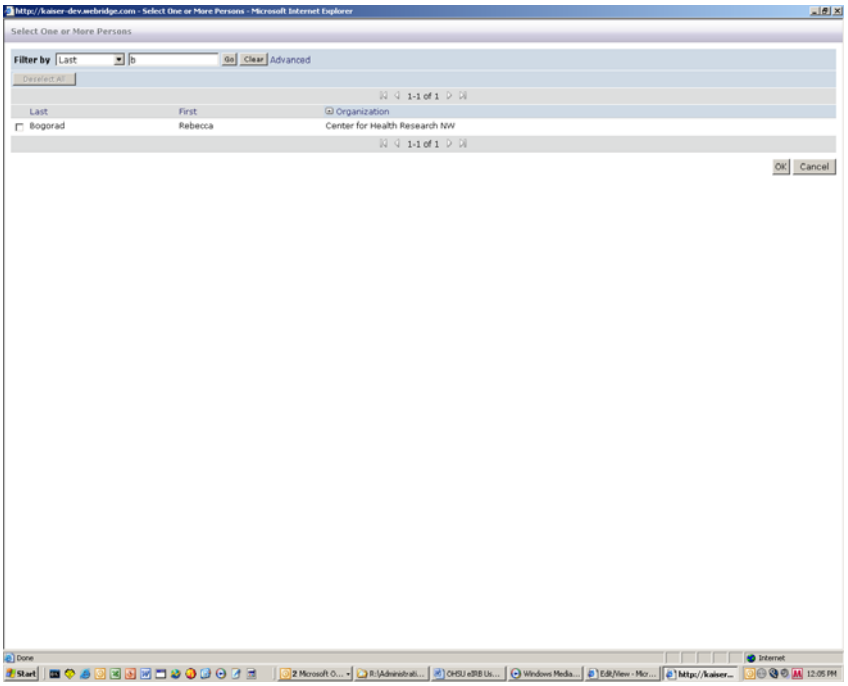


Figure 9

The personnel listed as PI or study staff will receive notifications about submissions as the review process progresses. These notifications contain working links to the submission workspace. Read the notifications carefully as *some are merely informative* and do NOT require any action from the study (see Figure 9a).

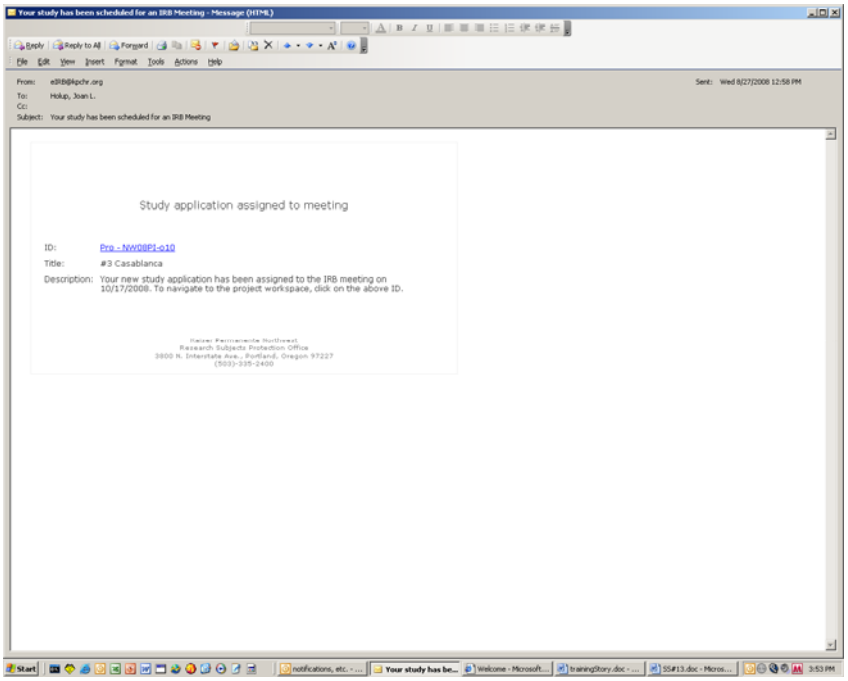


Figure 9a

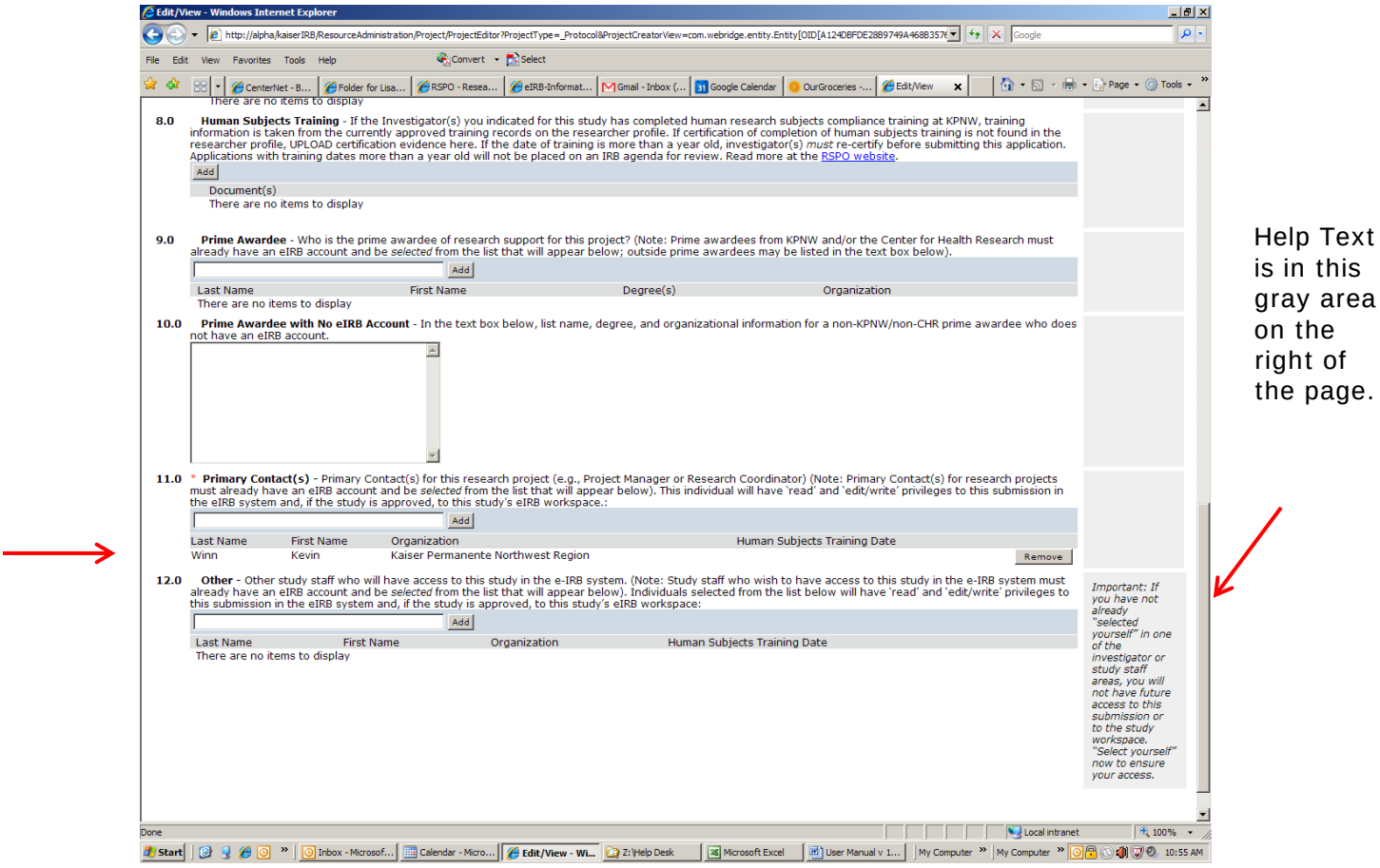


Figure 10

Human subjects training

The date of completion of KPNW human subjects training will be stored in user profiles. Information will be imported from the training system's database into the eIRB system periodically. If you, or someone on the study submission, has just completed human subjects training, and if the submission must go in right away, contact the eIRB Help Desk to request an unscheduled/immediate system update (see Figure 11).

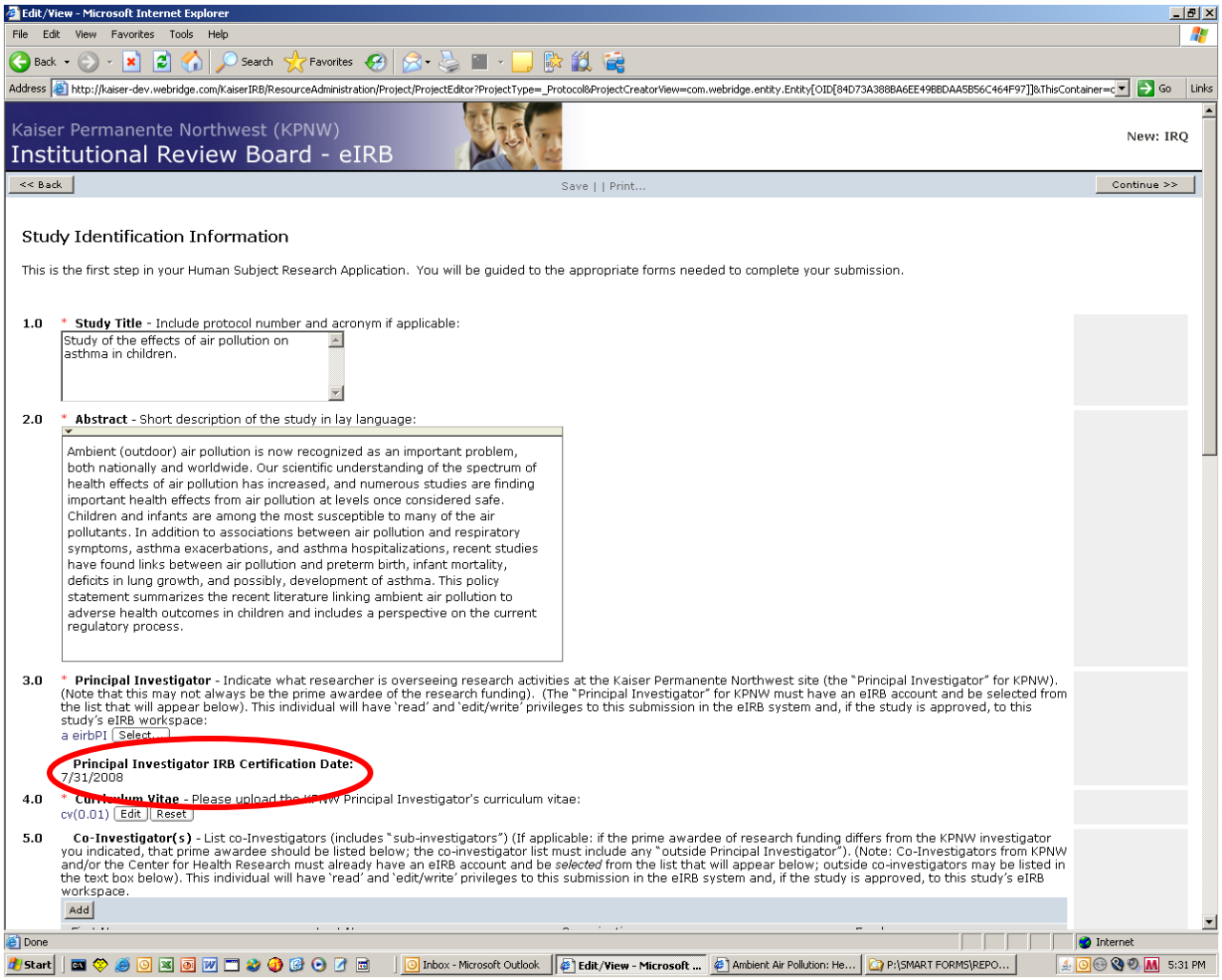


Figure 11

Updating study staff

The 'Edit study staff' activity located under 'My Activities' in the study workspace (see Figure 12) allows you to quickly change the study staff who either have been added to or have left a study; (to learn more about 'activities' generally, see: *Glossary: Understanding 'Activities'* near the end of this manual). Updating study staff is important to ensure appropriate staff are receiving notifications from the IRB regarding the study (e.g., continuing review reminders). This 'Edit study staff' activity is available in most states once a study has been submitted, including pre- and post-approval states. IRB approval is NOT required to change study staff on an approved study. Editing investigators on an approved study *does* require a modification request submission.

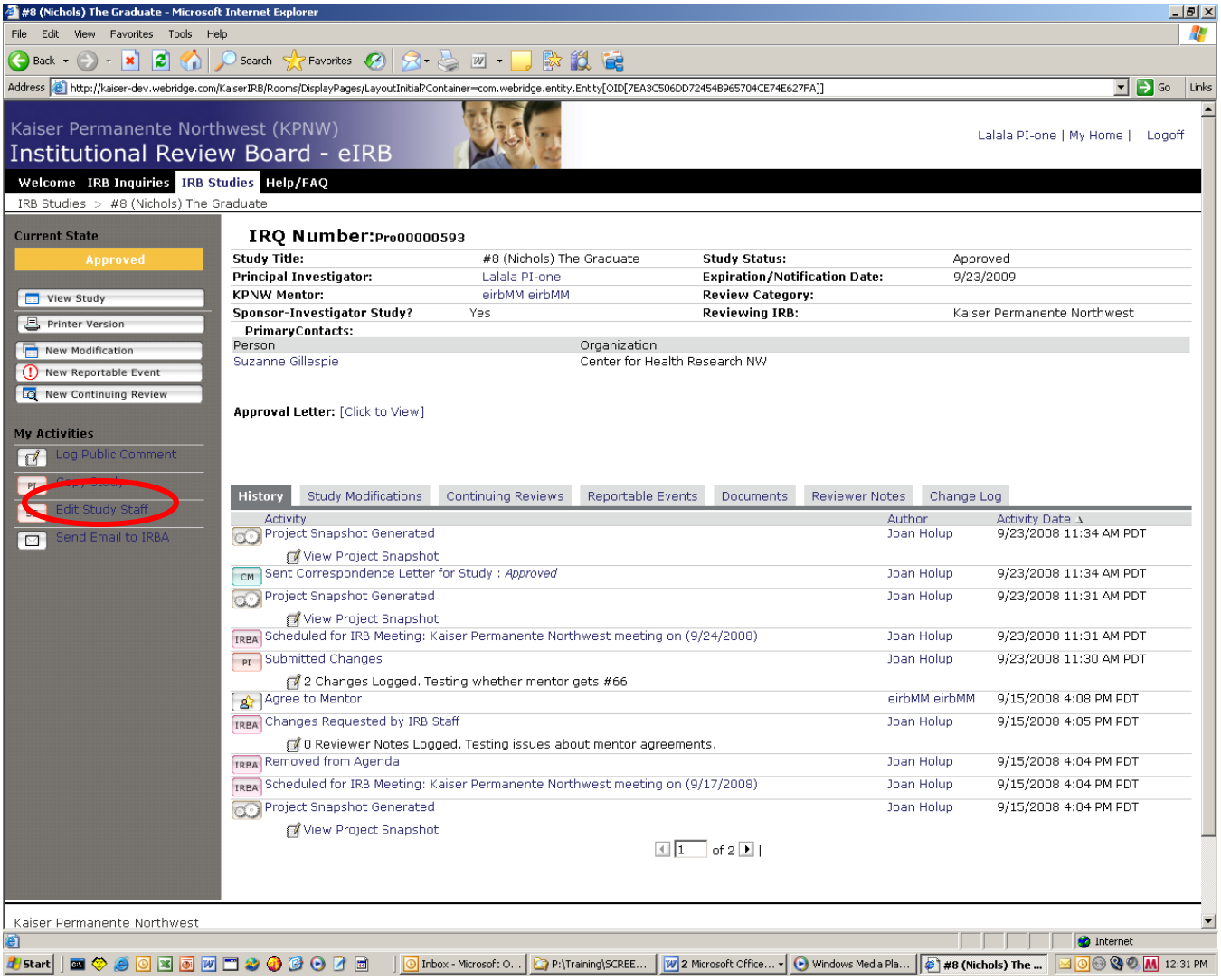


Figure 12

NAVIGATING THE INITIAL REVIEW QUESTIONNAIRE (IRQ)

Understanding 'Help Text Area'

Throughout the IRQ you can find the light-gray 'Help Text Area' located on the right section of each page (see Figure 10 a few pages back). The 'Help Text Area' contains useful hints and explanations, which will assist you in filling out the eIRB forms.

Searching lists

For some answers you will be asked to first try to select from a list rather than just typing-in your answer. For example, in the funder/sponsor questions you are asked to select from a list that is already within the eIRB system. In such areas, it may be helpful for you to use the following example of a search technique: If your funder is 'The Cancer Society' but you are not sure 'The' is really part of the funder's name, you can try to use a percentage sign as follows: enter '%cancer'. All funders and sponsors with the word 'cancer' anywhere within their name will be filtered and listed. Then, you can select your funder if it is found on the filtered list. If the funder/sponsor is not on the list in the system, enter the name in the text box provided.

Using the form drop-down list to 'Jump To' pages

The form drop-down list box (see Figure 13) is a convenient way to navigate through the IRQ if you do not wish to use the 'Continue' button and if you already know the name of the section

that you would like to modify. You must click on the down arrow next to the 'jump to' menu; do *not* click the text that says 'Jump to Menu'. The 'Jump To' menu will highlight your current page/screen in red font. It is very important to note that the form drop-down list box will display only the list sections that currently apply to your study. As you move through the form, the list may expand asnew required sections of the forms are completed. However, it is highly recommended that you use the 'Continue' button to progress through the application, as the system will then be smart enough to walk you through the proper branching and the submission will seem most 'logical' in terms of the progression of questions.

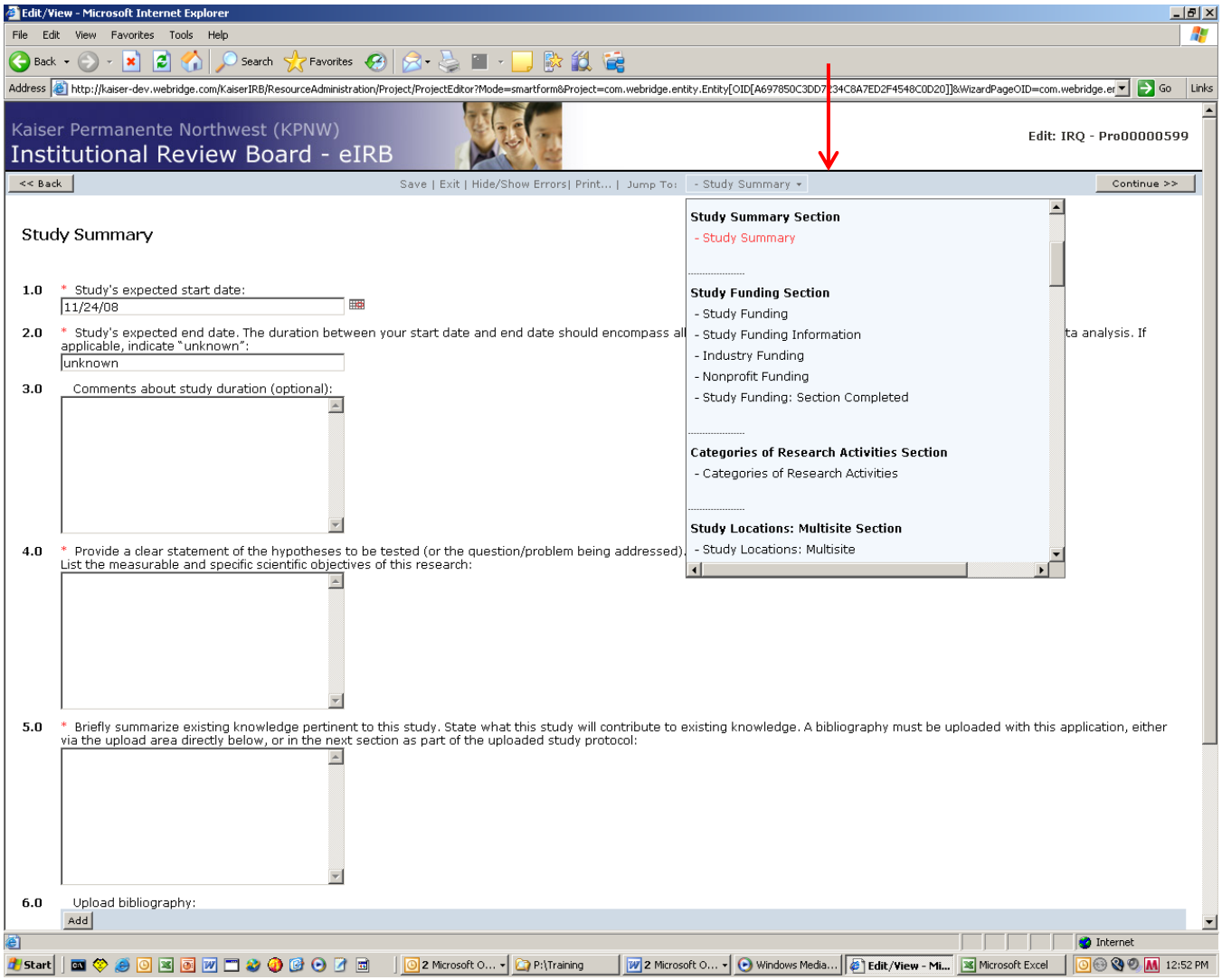


Figure 13

Saving the information you have entered

There are two ways to save information you have entered into the eIRB forms. You may use the 'Continue' button to automatically save all data entered into a form thus far. Or, you may use the 'Save' option. The latter will save the information, but will not automatically lead you to the next page/screen. It is important to save any work on a give page if you do not click the 'Continue' button.

Using Hide/Show Errors

The Hide/Show Errors link, located in both the upper and the lower center of the blue menu bar of the form, allows you to check for any required questions that have been omitted. The links

that display in the Errors/Warning messages window allow you to jump directly to the required question and answer it. Once you have answered the question, click on the 'Save' link and then click on the 'Refresh' button located in the lower right section of the page. Repeating this process will remove errors from the list as they are corrected until there are no errors left**.** *(To turn off the error display entirely, click on the 'Hide/Show Errors' one more time).* See Figure 14. Please note that the PI will **not** be able to submit the study if there are any required questions that remain unanswered.

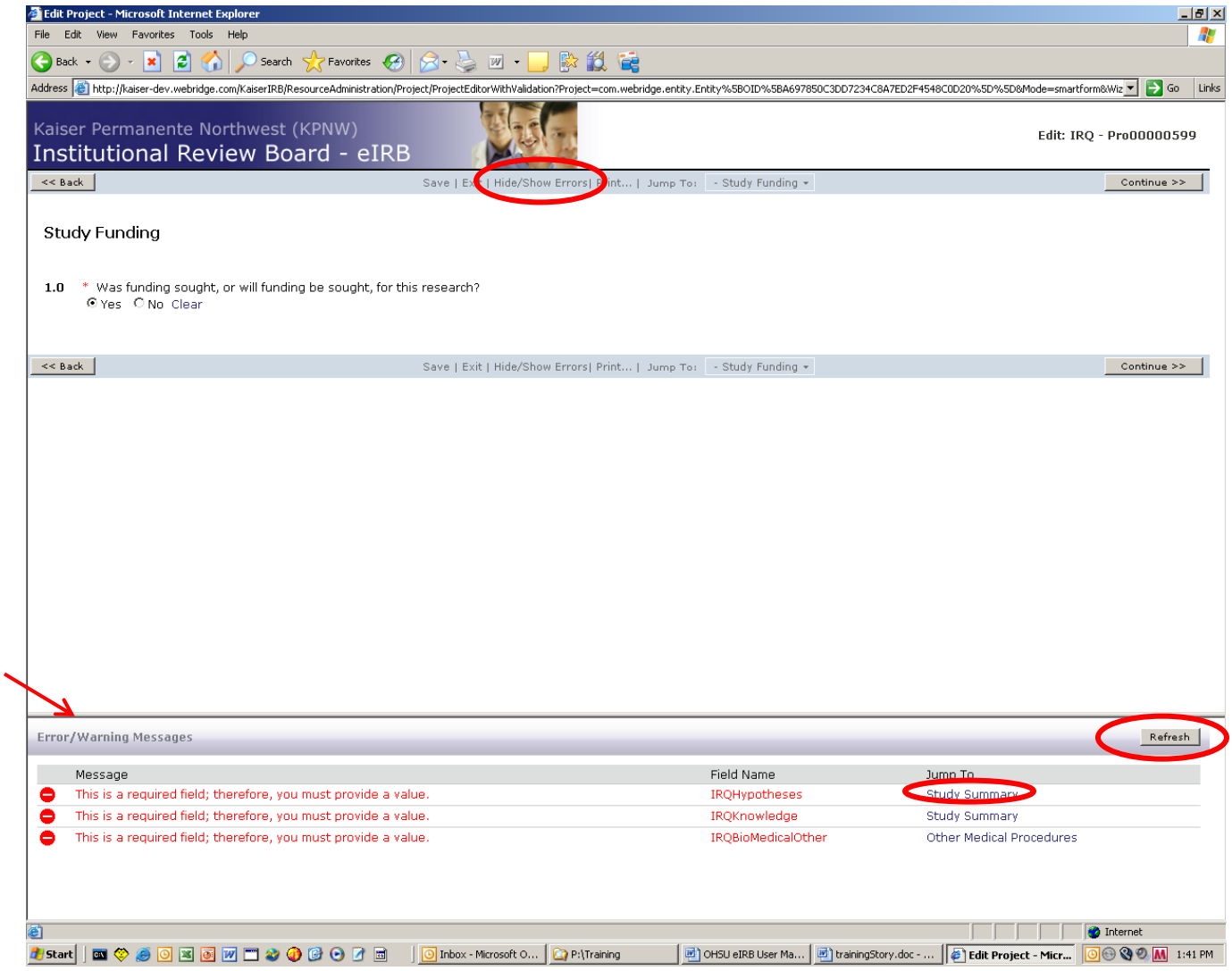


Figure 14

Exiting the Form

Before exiting it is important to save your answers by clicking the 'Save' link.

To exit the IRQ please use the 'Exit' link. If applicable, when you click on the 'Exit' link, a standard warning window will open asking you/reminding you to save your answers. If you have not saved your answers and *wish to*, click 'OK' and the system will save your changes and automatically 'exit' you from the submission. If you have not saved your answers and do NOT *wish to save them*, click 'No' and the system will not save your changes and automatically close your submission (see Figure 15).

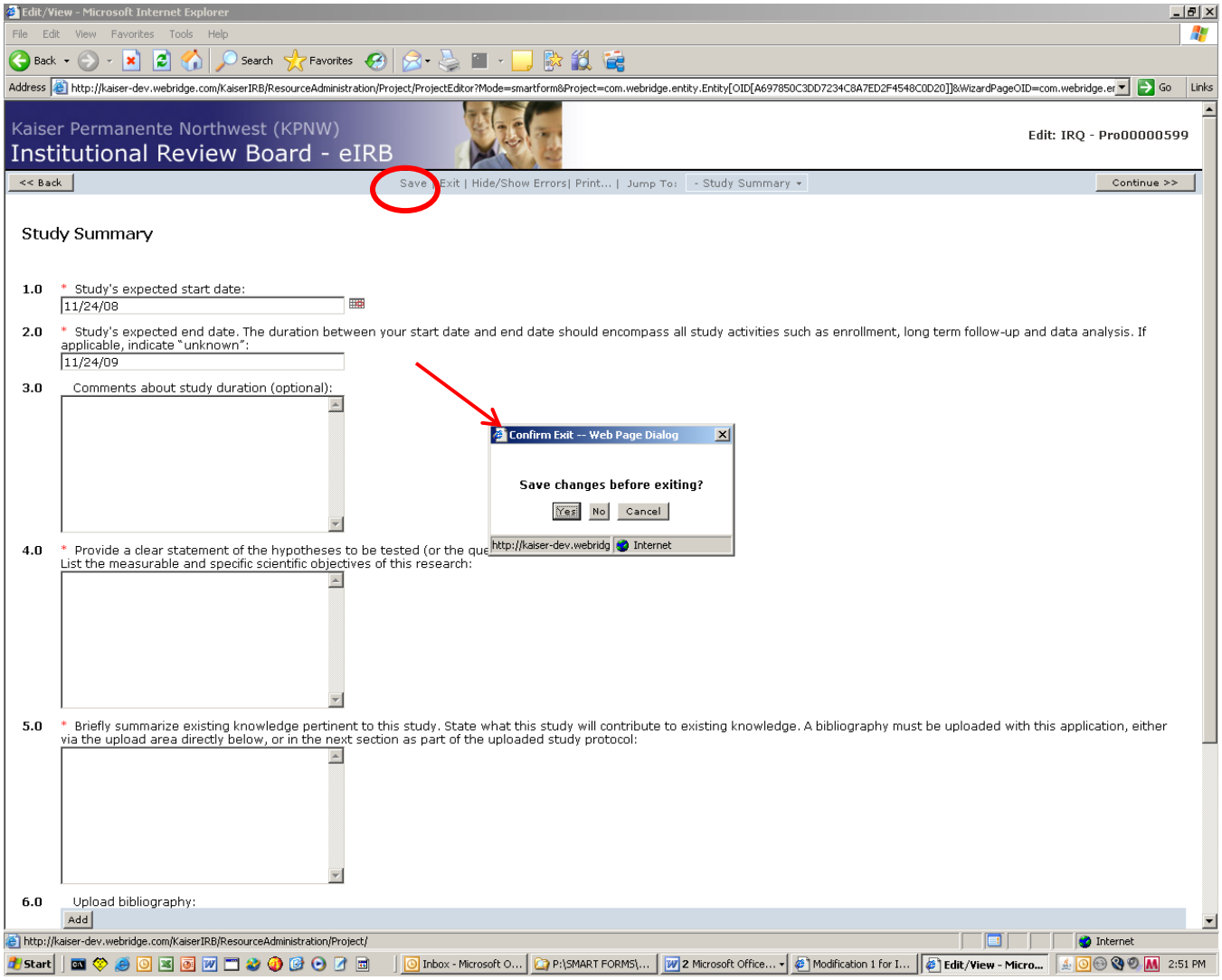


Figure 15

Uploading documents

In various places in the eIRB forms, you may be asked to upload documents. For example, if you are doing primary data collection (collecting information or samples directly from participants), you will be asked to upload any recruitment materials to be used on the study (see Figure 16).

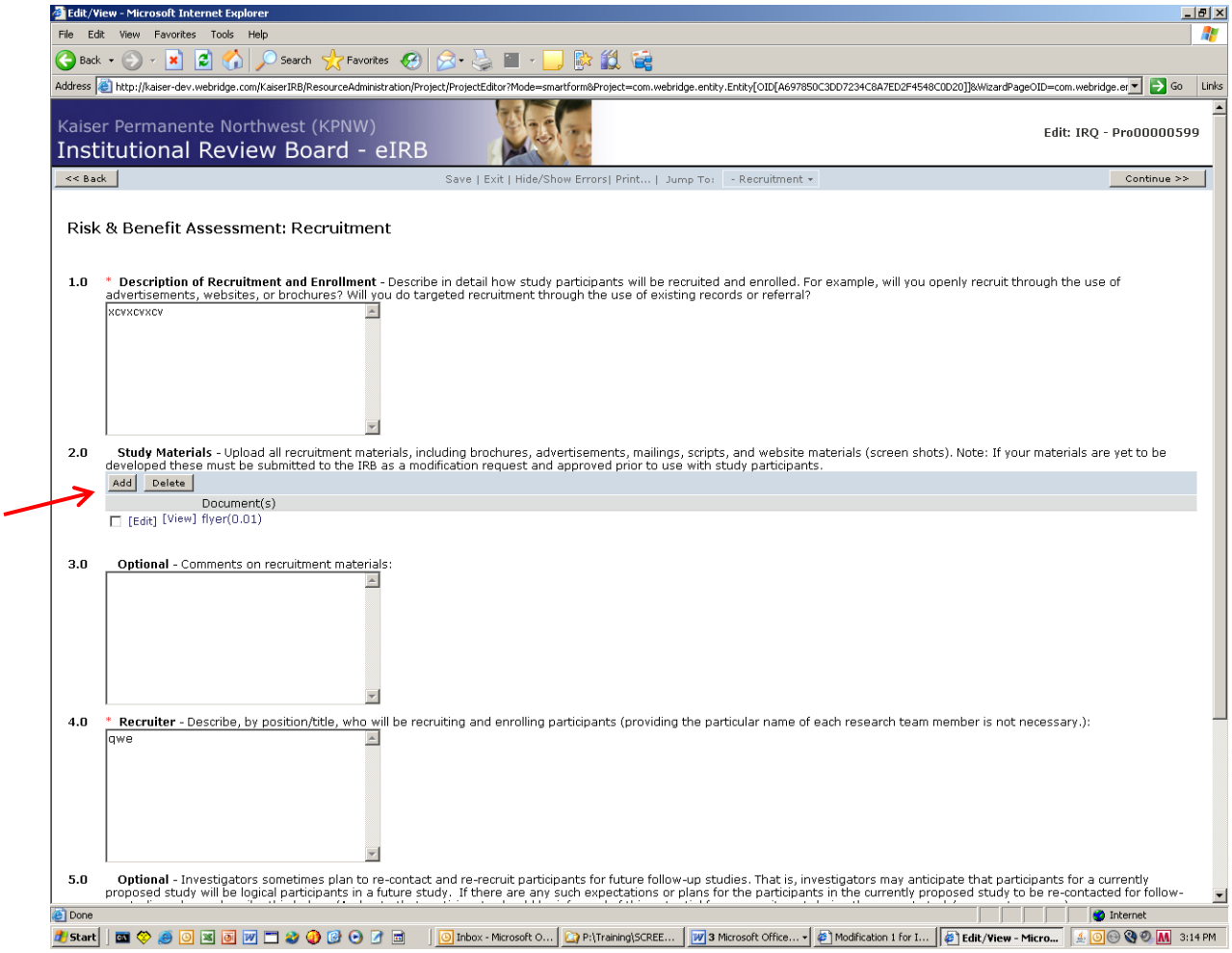


Figure 16

In addition to the standard documents that are requested throughout the IRQ form (such as consent forms or a protocol) there is a place for 'other' documents to be uploaded at the end of the submission. Use this option *if* you have progressed through the submission process to the end *and have not had a logical/designated place to upload a certain document* (see Figure 17). You are strongly encouraged to use this 'general' area only when there has been no other logical place to upload the material. Following this rule will help your study team and the IRB *later* when you need to make modification requests related to documents.

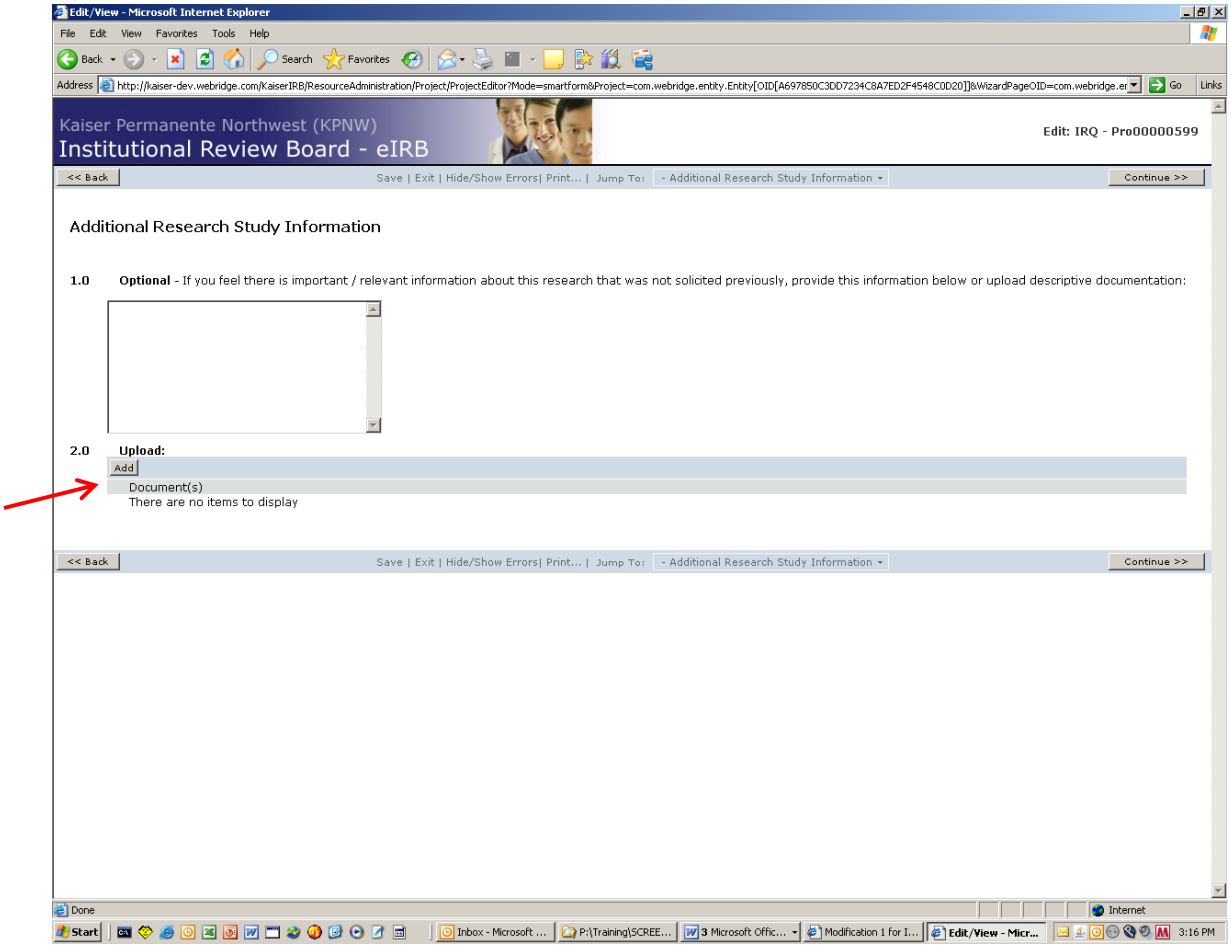


Figure 17

The eIRB will allow you to upload electronic documents of any type and format. It is important to keep in mind that the reviewer of these documents, such as an RSPO employee or IRB reviewers, must have the same software application as you to be able to open and read the uploaded document. When possible, use standard software applications available on KPNW workstations, such as Microsoft® Word, Excel, PowerPoint, and Adobe Acrobat Reader.

Most document upload areas allow you to upload multiple documents (if that is needed on your study). Click on the 'Browse' button in order to locate the document you would like to upload. You may provide a title for the document(s) you upload. If you do not title the document(s), the file name(s) will be used as a default (see Figure 18).

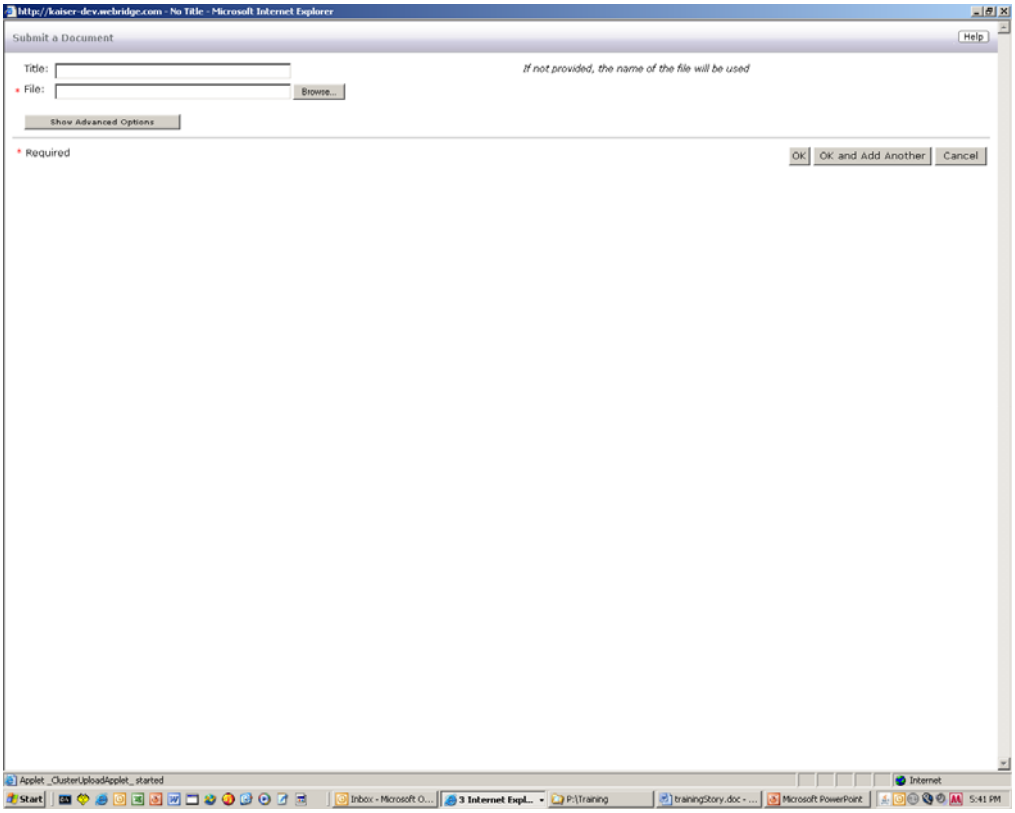


Figure 18

Once you have located the document on a network-drive, select the document, click the 'Open' button (see Figure 19) and then click the 'OK' button on the document upload window (or click 'OK and Add Another' if you wish to upload multiple documents).

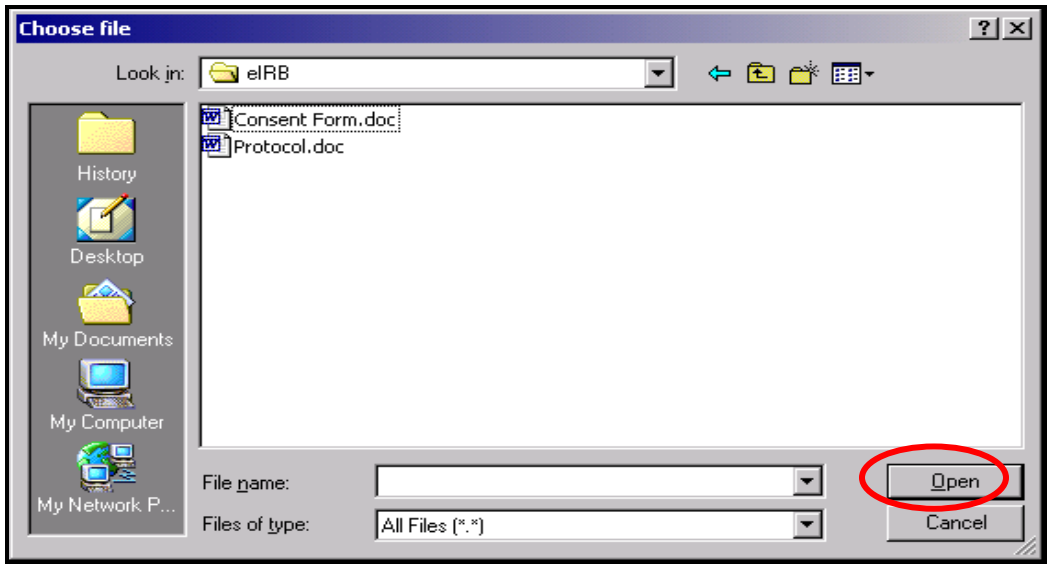


Figure 19

Deleting documents

If you mistakenly upload a document and need to remove it, place a checkmark next to the document and then hit 'Delete'. A message will appear asking if you are sure you want to delete the document. Indicate 'OK' to delete the document. Be aware that deleted documents may not be retrieved within the eIRB. You would need to upload them again from your file service. See Figure 20.

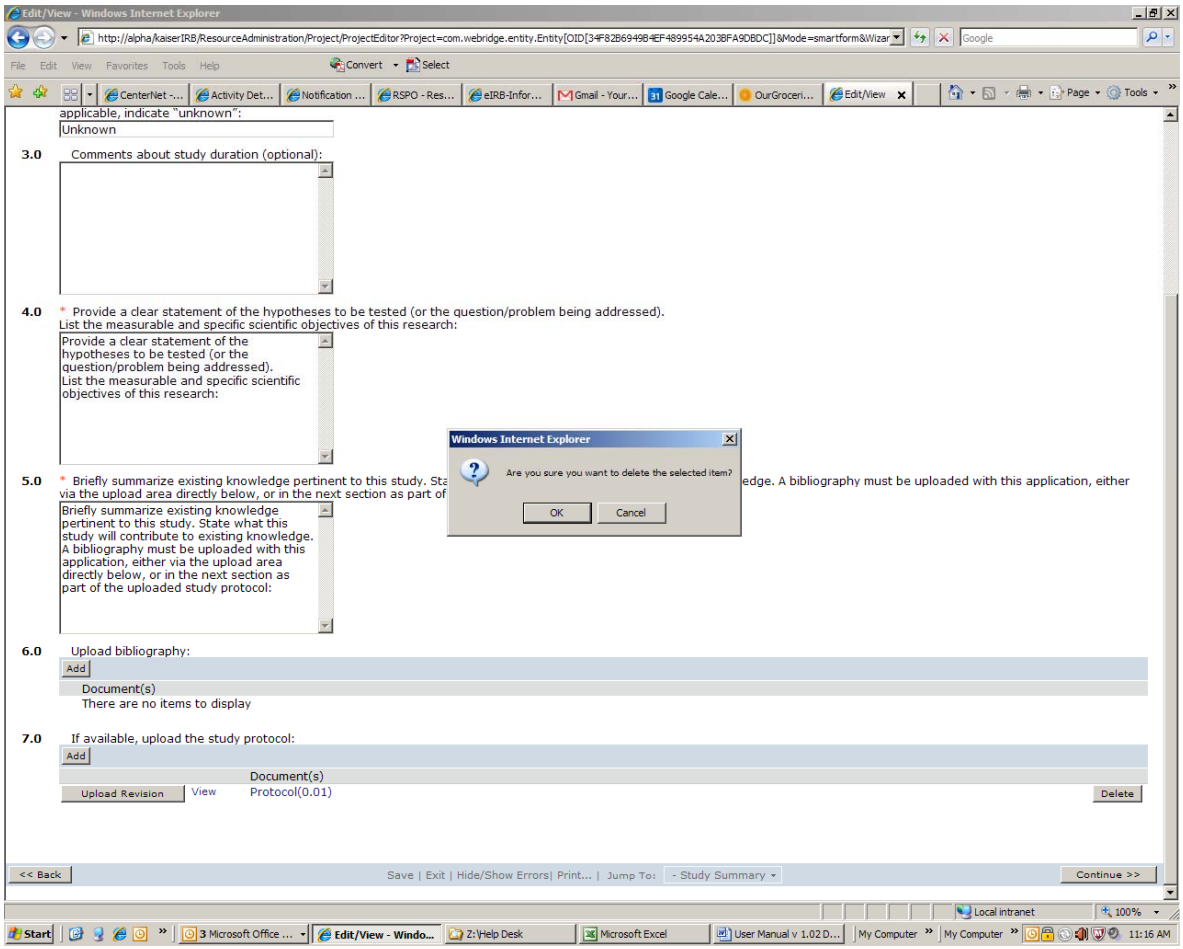


Figure 20

You may get the following (Figure 21) the first time you attempt to upload a document into the IRQ. Check the 'Always trust' and click on 'Run'.

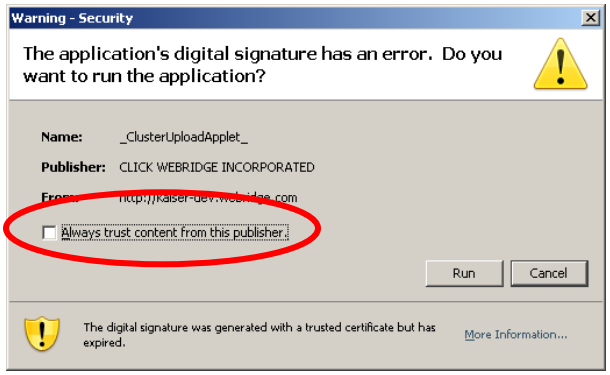


Figure 21

You may also be presented with the following message if the eIRB system is *already* in the process of uploading a file into your submission and you attempt to upload the file again: 'You have already submitted the current form. Please wait and the operation will be completed momentarily'.

Editing / replacing uploaded documents

If you wish to upload an edited or newer version of the document, click the 'Edit' link in front of the document and repeat the upload procedure. Click the 'OK' button in order to close the window. The document version will be automatically incremented (Version 0.01 to Version 0.02, etc.).

Note that the 'Title' field of the navigation window will not update the title of the document (Figure 22).You may either rename the title of the document or clear the field if you want the document title to be retained from your files (the file path will not be included in the title).

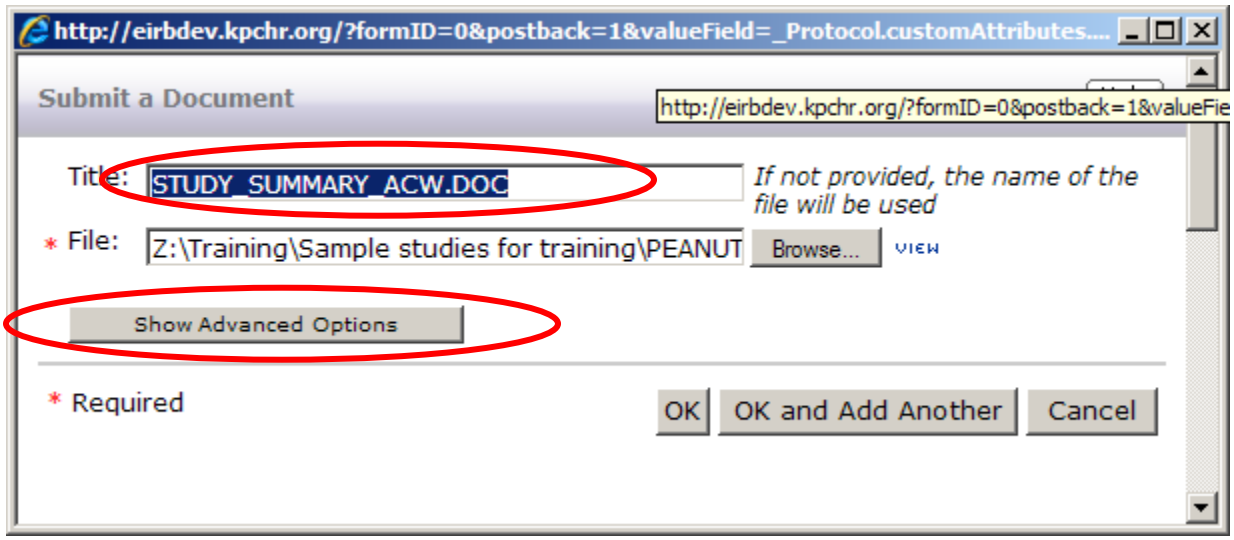


Figure 22

The eIRB maintains a history of all subsequently uploaded documents and allows you to rollback to a previous version. This function can be accomplished by clicking the 'Edit' link in front of the document, and then by clicking on the 'Show Advanced Option' button. Once the advanced options are displayed, click on the 'History & Roll Back' link (Figure 23). You may now click on a previous version of a document to view it, or select the document you wish to 'rollback to', followed by clicking the 'OK' button.

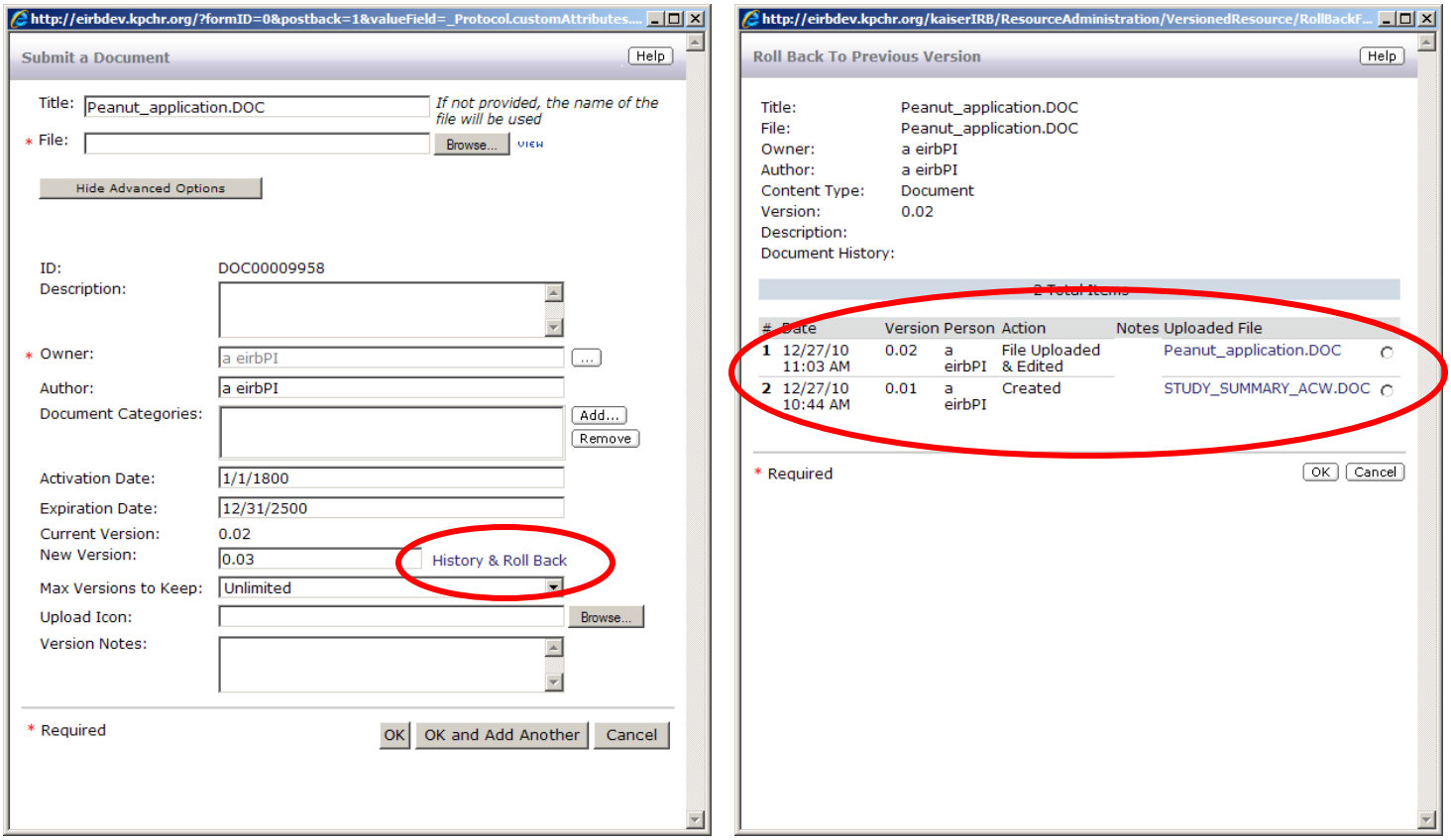


Figure 23

STUDY WORKSPACE OVERVIEW

When you create a Study, Continuing Review, Reportable Event, Modification, or IRQ Inquiry, a comprehensive area referred to as the 'project workspace' is created, which displays useful information about the submission (see Figure 24).

In a project workspace, the submission's 'numbered number' is displayed in bolded letters near the top. When speaking with eIRB technical support staff or with RSPO staff, refer to the last digits of the ID number, omitting the zeros. In Figure 24, this would be number '593'.

The yellow area indicates the **Current State** of the review process for the particular submission. As the review progresses, the state change. (*See GLOSSARY: Understanding 'Current States' for more detail*).

My Activities lists the activities available to you in the *Current State* of the review process for the particular submission. As the review progresses, available activities will change. (*See GLOSSARY: Understanding 'Activities' for more detail*).

Note: When a submission is in a 'pre-submission' state, this is the area where the PI would find the 'Submit' activity.

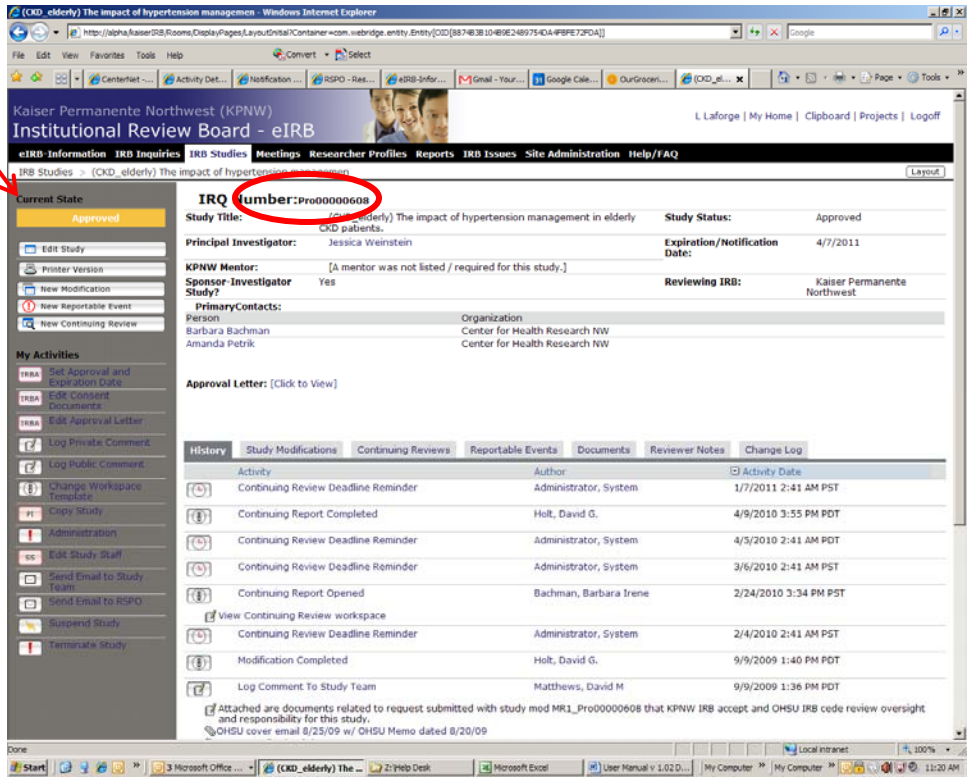


Figure 24

Study Workspace Details (Refer to Figure 24)

- 'Study Title' displays the first 50 characters of the title entered into the first field on the IRQ.
- Your 'Old IRB #', e.g., NW-08MHorn-04, will be displayed as the IRQ Number only if you have converted an existing study from paper.
- Once the study has been approved and given an IRB approval expiration date, that date will display on the workspace.
- If the study has a 'Mentor' assigned, the mentor's name will appear in the workspace.
- If the study has a KPNW sponsor-investigator, 'yes' will display. (This is for IRB administrative interest related to FDA-regulated studies only).
- The primary contacts listed on the IRQ are displayed.
- If there is an 'Approval' letter for the study, a link will be available to view.
- The tabs on the study workspace contain and, if clicked, will display:

  - **History -** Events associated with the IRB review of the study (see History tab, figure 24). Note that new studies and *other* types of submissions (Study Modifications; Continuing Reviews; and Reportable Events) also have their *own* history tabs that display events in their review process.

  - **Submissions -** subsequent to the initial submission (Study Modifications; Continuing Reviews; and Reportable Events tabs, see figure 24a);

- **Documents** - When new study documents are 'approved,' or once documents are subsequently approved through a Modification Request, this tab will automatically 'update' to display current versions; (Documents tab, see figure 24b)

and

- If applicable, reviewer notes and a change log for the study.

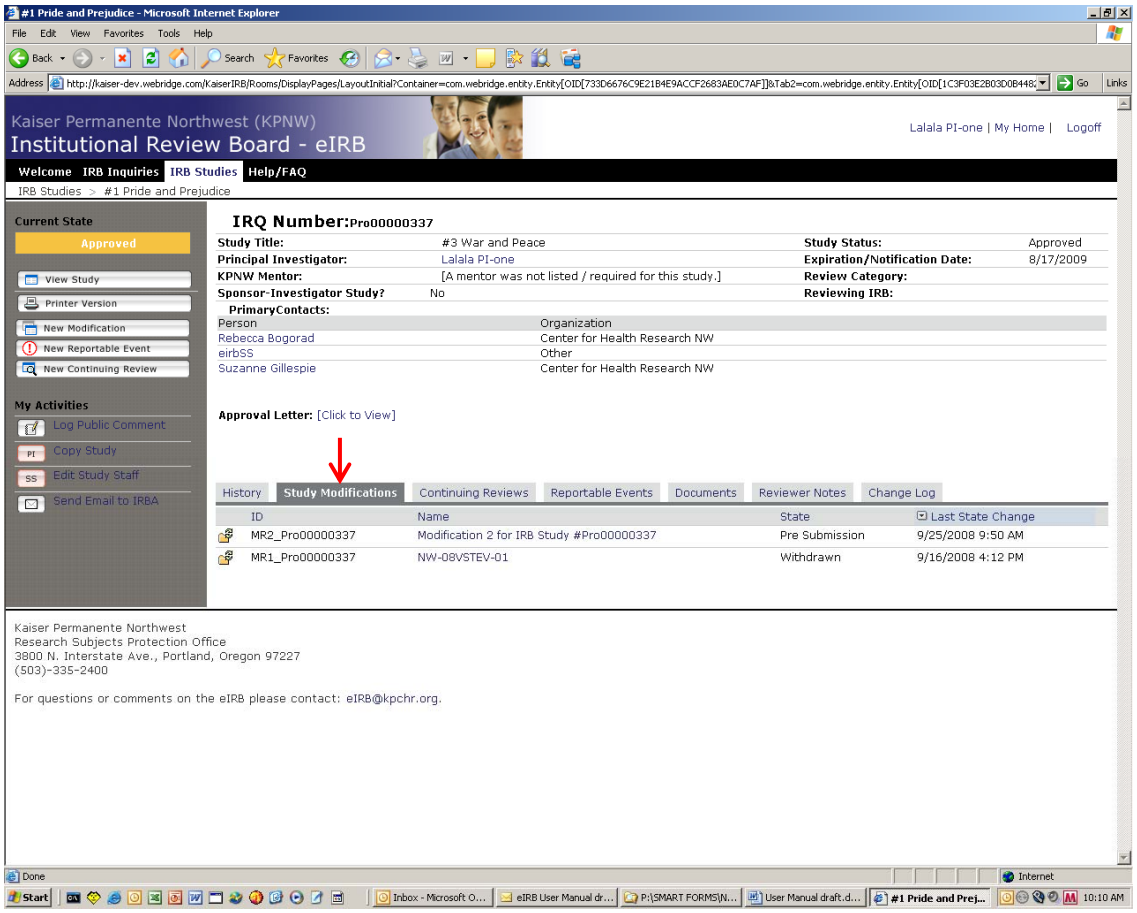


Figure 24a

Important Note – The RSPO manages informed consents in the eIRB. Once a consent form is approved, the RSPO staff will upload a clean version of the consent in the 'Draft Informed Consent Materials' area of the Documents tab. A PDF version of the consent with the IRB approval key will be uploaded in the 'Approved Consent Forms' area.

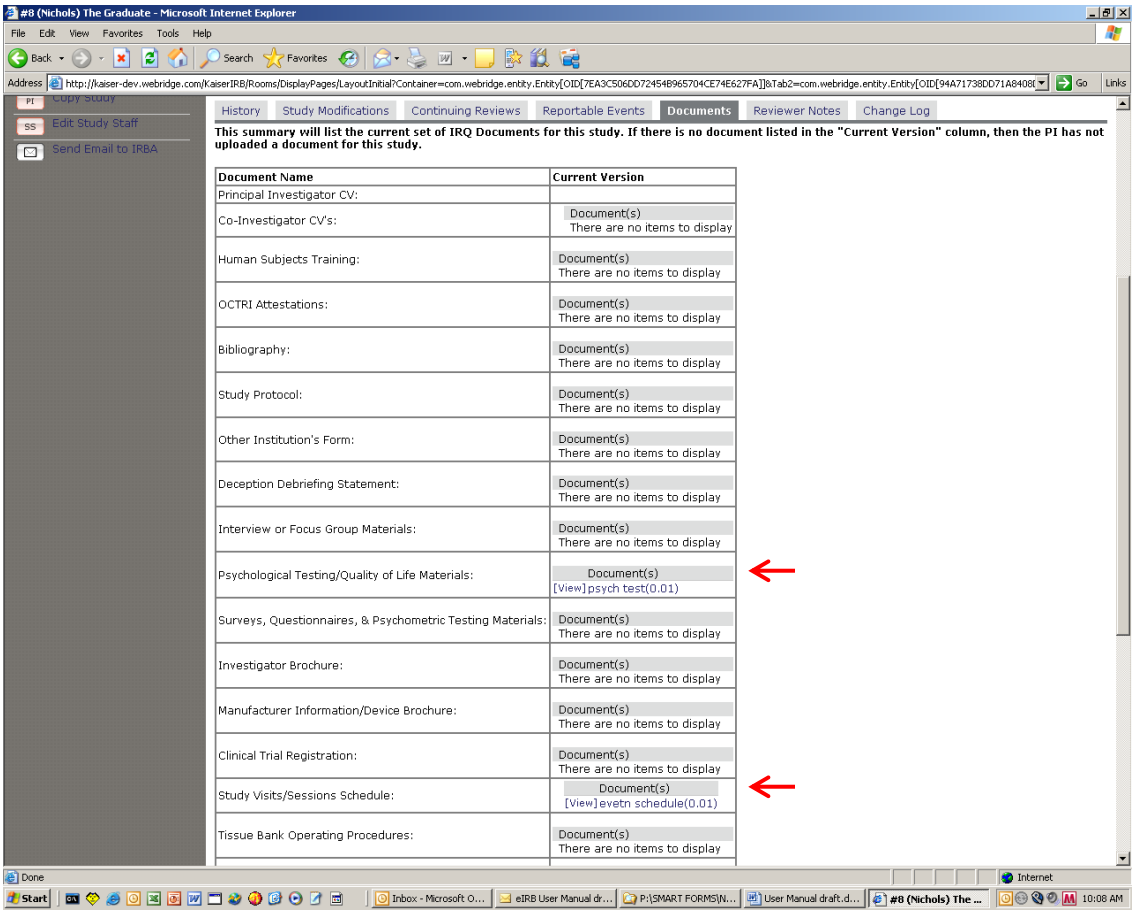


Figure 24b

Printing, saving, and documenting submissions

There is a Printer Version feature within the system for printing hardcopies of the submissions and saving a copy of the submission as an electronic file. See the Printer Version button in the left area of the submission workspace (see Figure 24). You are encouraged to primarily rely on the eIRB system itself for 'documentation', since the system is designed to provide a sufficient project history, record of submissions, and record of IRB approvals. KPNW's adoption of an eIRB system can result in cost savings and significant environmental benefits, if fewer hardcopies are associated with the IRB process. The Project Snapshot that runs at designated points in the review process and is found in the History tab is another method used to 'freeze and capture a snapshot in time' of a study submission.

Submitting

Only the PI on a study has the option to submit the new study, continuing review, reportable event, or modification request (equivalent to a signature on paper).

If you are not the investigator and you have drafted a submission form: Once you have drafted/filled out the initial review questionnaire (IRQ), continuing review, reportable event, or modification request, you must then notify the PI that the draft is ready for him or her to review and submit. You may provide the PI with the IRQ number and/or the study title for reference. If she or he is listed as the PI within the study submission (see question 3 on figure 11 earlier in this manual), the drafted submission should display in the PI's inbox in a state of 'pre-submission'.

The PI must submit the form (regardless of who drafted the form. Once the PI has ensured that the submission is accurate and ready for IRB review, the PI will click on the 'Submit' activity

located on the left section of the submission workspace page under My Activities. If it is a new study submission, the PI will be presented with, and will need to check, a number of attestations as part of the 'submit' activity. Once the submit action has been completed, the submission will move to a state of 'IRB Staff Review', and will have entered the review process.

CONVERTING EXISTING HARDCOPY STUDIES INTO THE eIRB

If your active study is currently on paper and you are planning to do any IRB submission (including continuing review) soon, you MUST first convert your active hardcopy study to the eIRB, by selecting 'New Study' located in the upper left section of the 'My Home' page (see Figure 25).

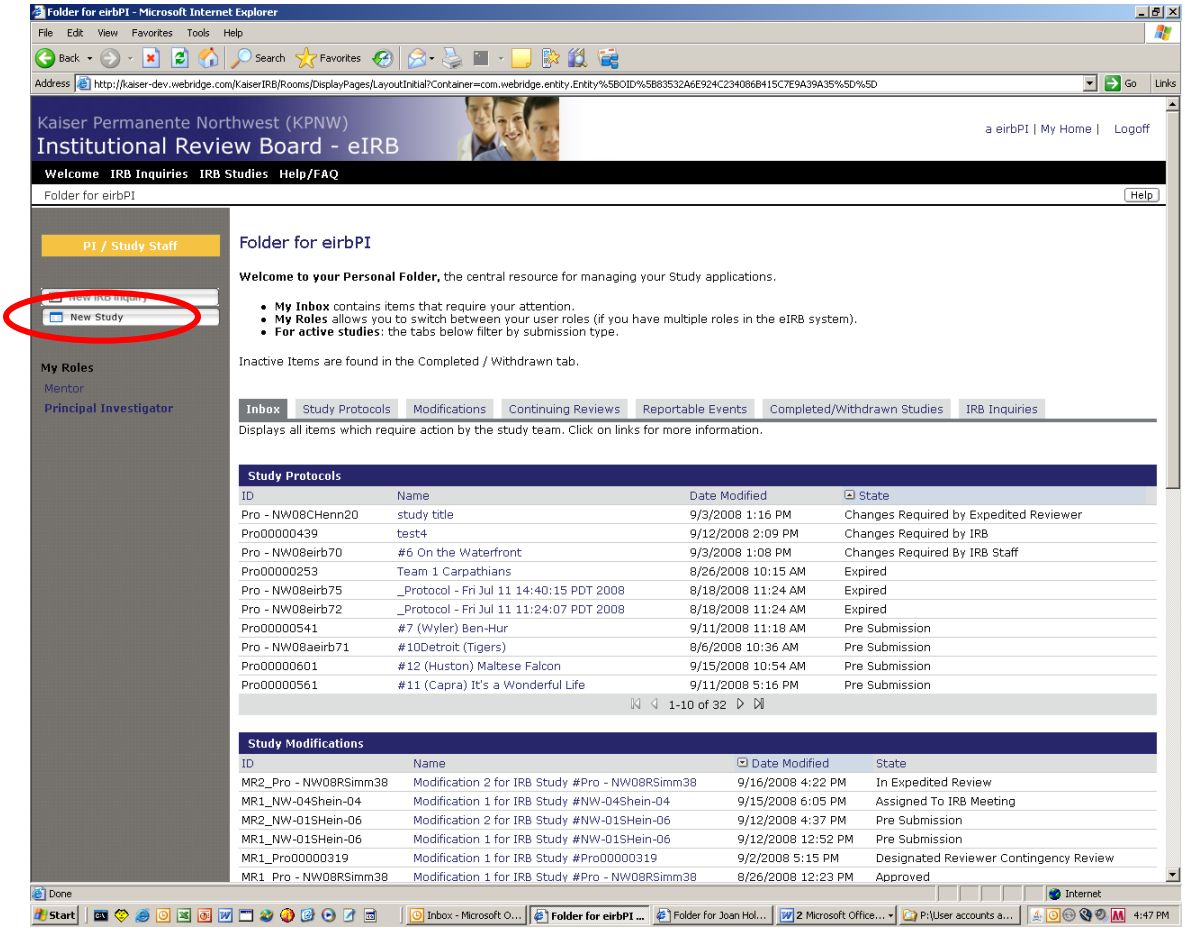


Figure 25

The Initial Review Questionnaire (IRQ) will open. Enter information on the first page and click 'Continue'. On the next screen, for the type of submission, choose the option 'A conversion of an existing (already IRB-approved) paper study into the eIRB' (see Figure 26). This will branch you through an abbreviated version of the IRQ. Use the 'Continue' button to navigate through the rest of the questionnaire and answer all applicable questions. On the last page click 'finish' to complete the questionnaire.

Once the IRQ for the converted study has been drafted, the study PI will 'submit' it. The RSPO office will expedite the 'Approval' of the study in the system in order to 'create' the study within the eIRB. Once the status changes to 'Approved', you will then have the option to create other submission types for the study, such as a continuing review, modification request, etc.

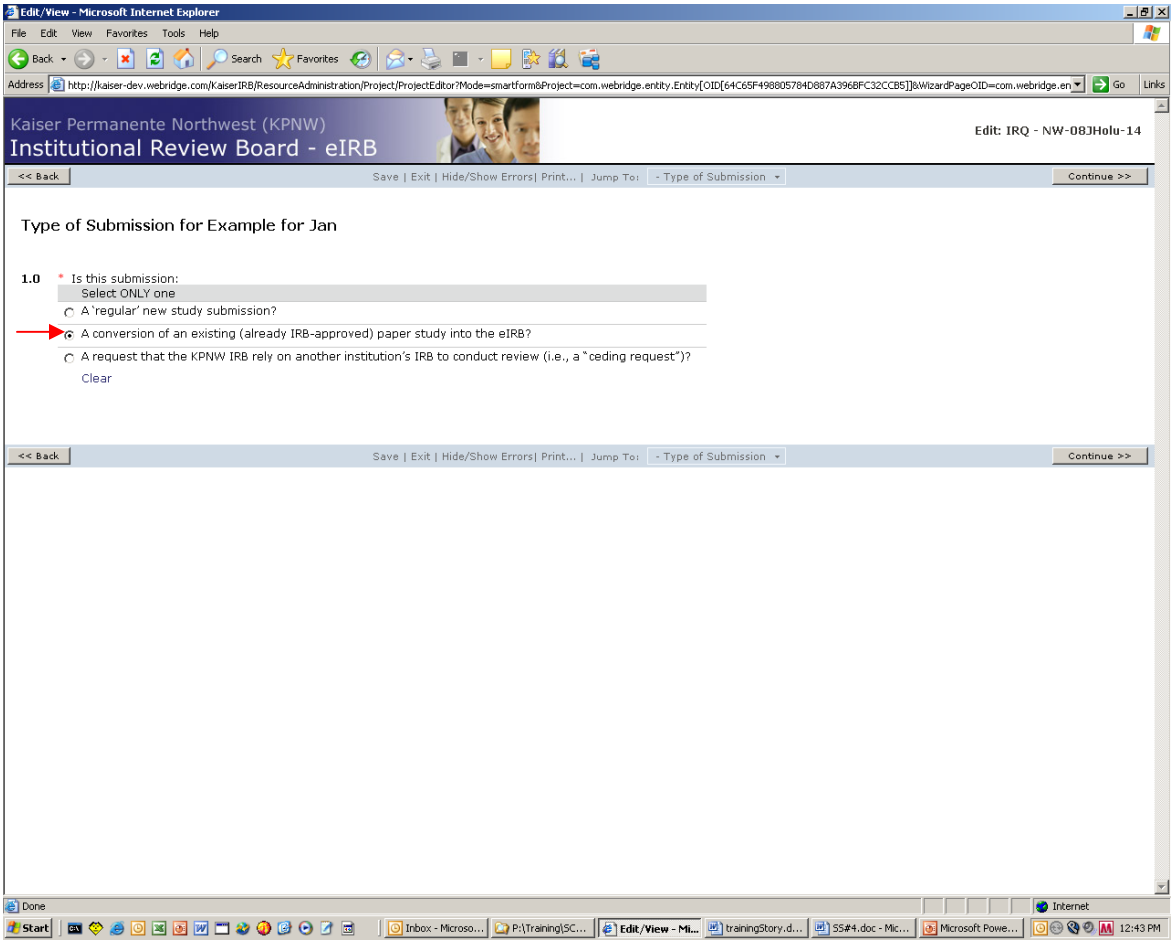


Figure 26

CREATING CONTINUING REVIEWS

Before you can create a continuing review, you must have an active/approved study in the eIRB. If you already have an active paper study, you may convert it in the eIRB. For details on converting an existing study, read the section of this user manual 'Converting Existing Hardcopy Studies into the eIRB'.

In order to create a continuing review, open your active study. In the left section of the page, click on the 'New Continuing Review' button (see Figure 27). You may only initiate and be drafting one continuing review at a time on a given study, and you may only have one continuing review *submitted* at a time for any given study.

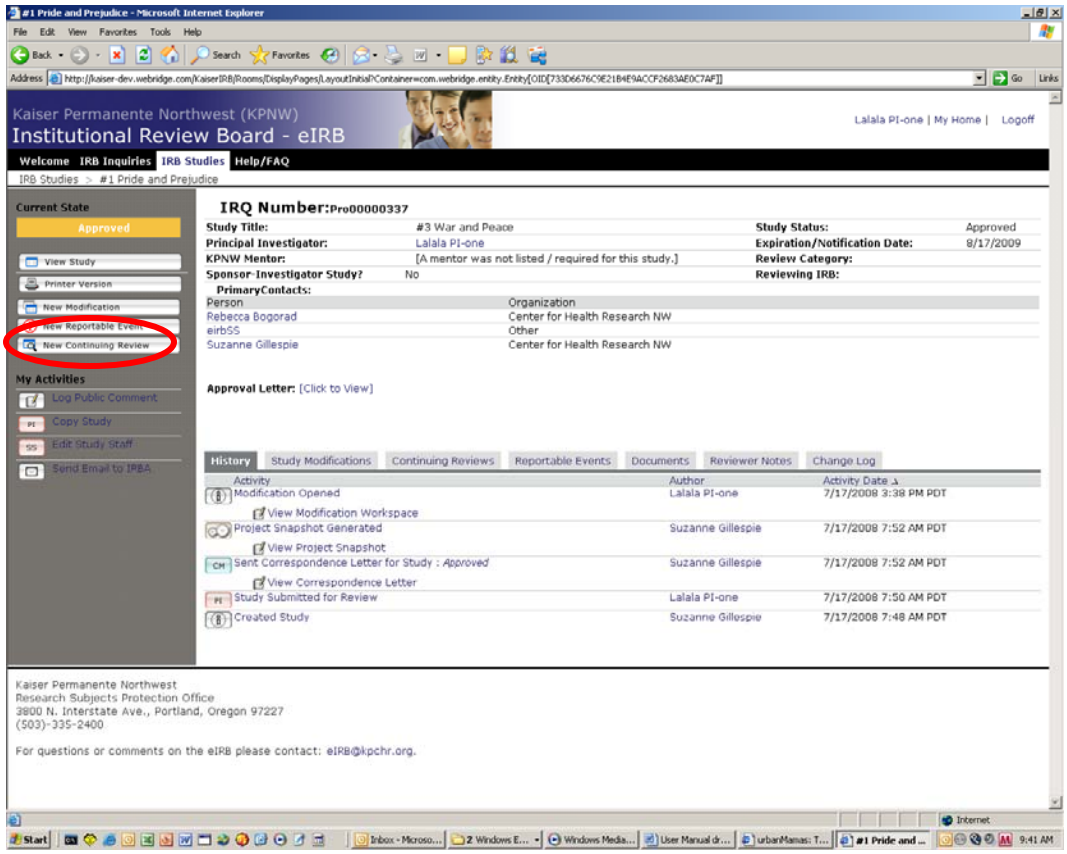


Figure 27

Initially, the form will prompt you to indicate whether you are submitting a final or progress report, and ask for a short name that briefly describes your continuing review (see Figure 28). Use the 'Continue' button located in the upper and in the lower right portion of the page to navigate through the form while answering all applicable questions page by page. On the last page click 'finish' to complete the questionnaire. Once the continuing review is complete and error-free the PI should submit it for review using the 'submit activity' (see submission section above).

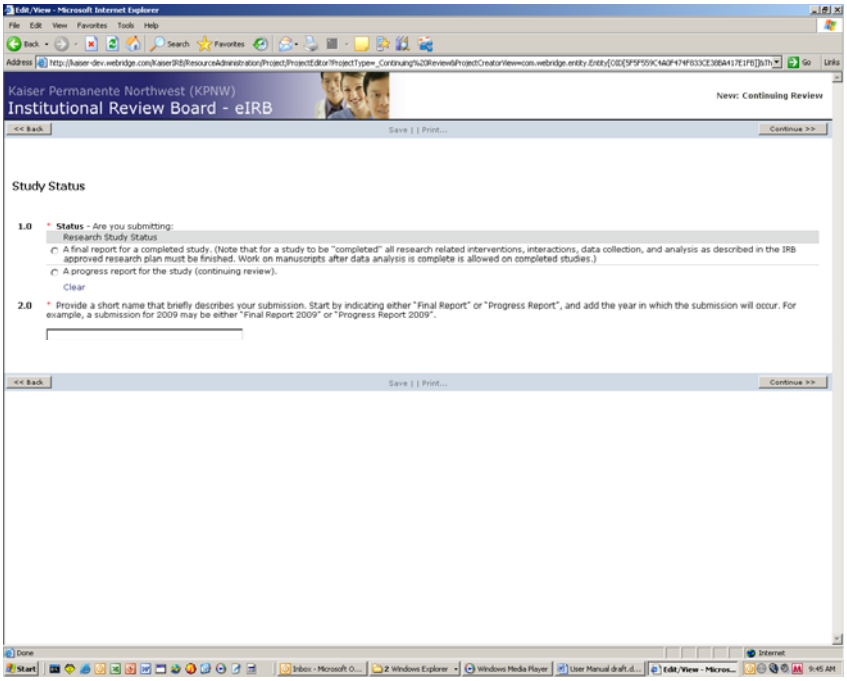


Figure 28

CREATING MODIFICATION REQUESTS

Your study must be 'active and approved' in the eIRB before you submit a modification request on the study. (If you already have an active paper study, you may convert it in the eIRB. For details on converting an existing study, read the section of this user manual 'Converting Existing Hardcopy Studies into the eIRB'). Once you have opened your active study, click on the 'New Modification' button located in the left section of the study workspace (See Figure 29).

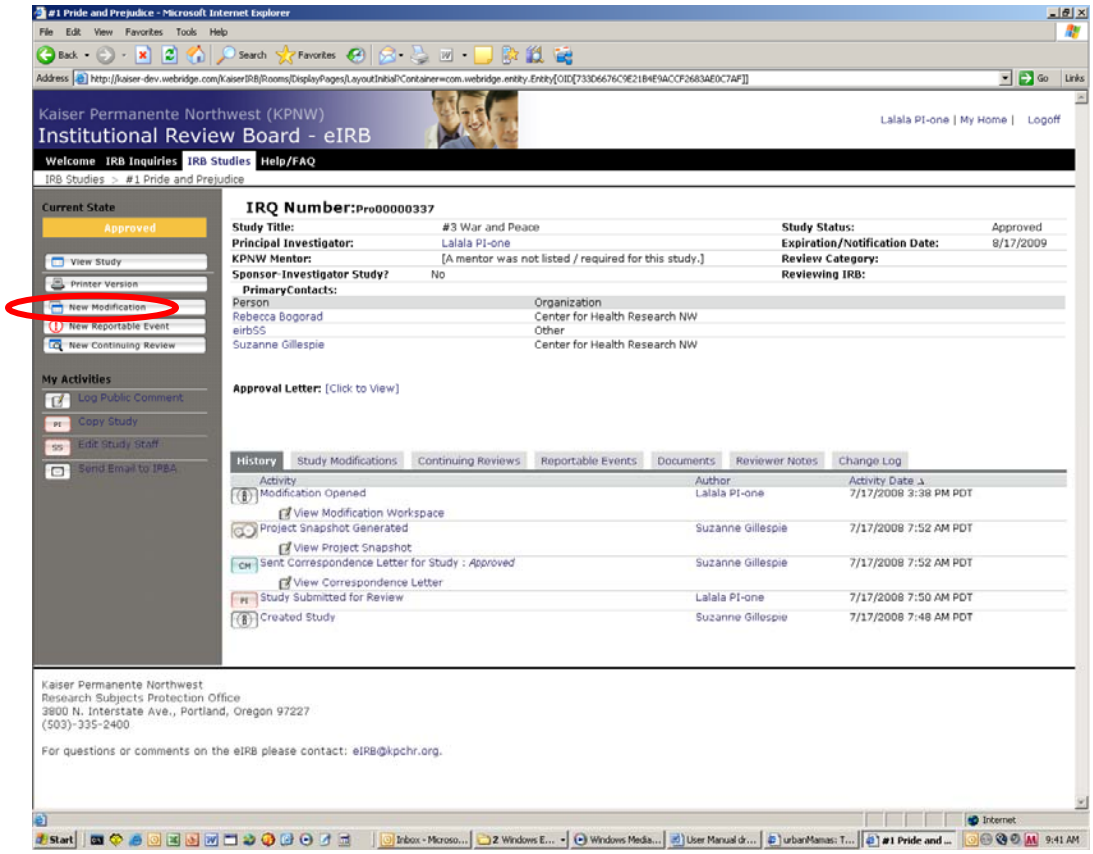


Figure 29

On the first screen, provide a short name for your submission. The name of the submission should be a short description of the modification(s) being requested. For example, 'Change PI'; 'Revise Consent Form'; or 'Change PI and revise consent and recruitment docs'. The name of the submission should not exceed 50 characters with spaces (see Figure 30). The RSPO will use this description will be included in the approval letter for the modification. Therefore, the description should contain no abbreviations and should be grammatically correct.

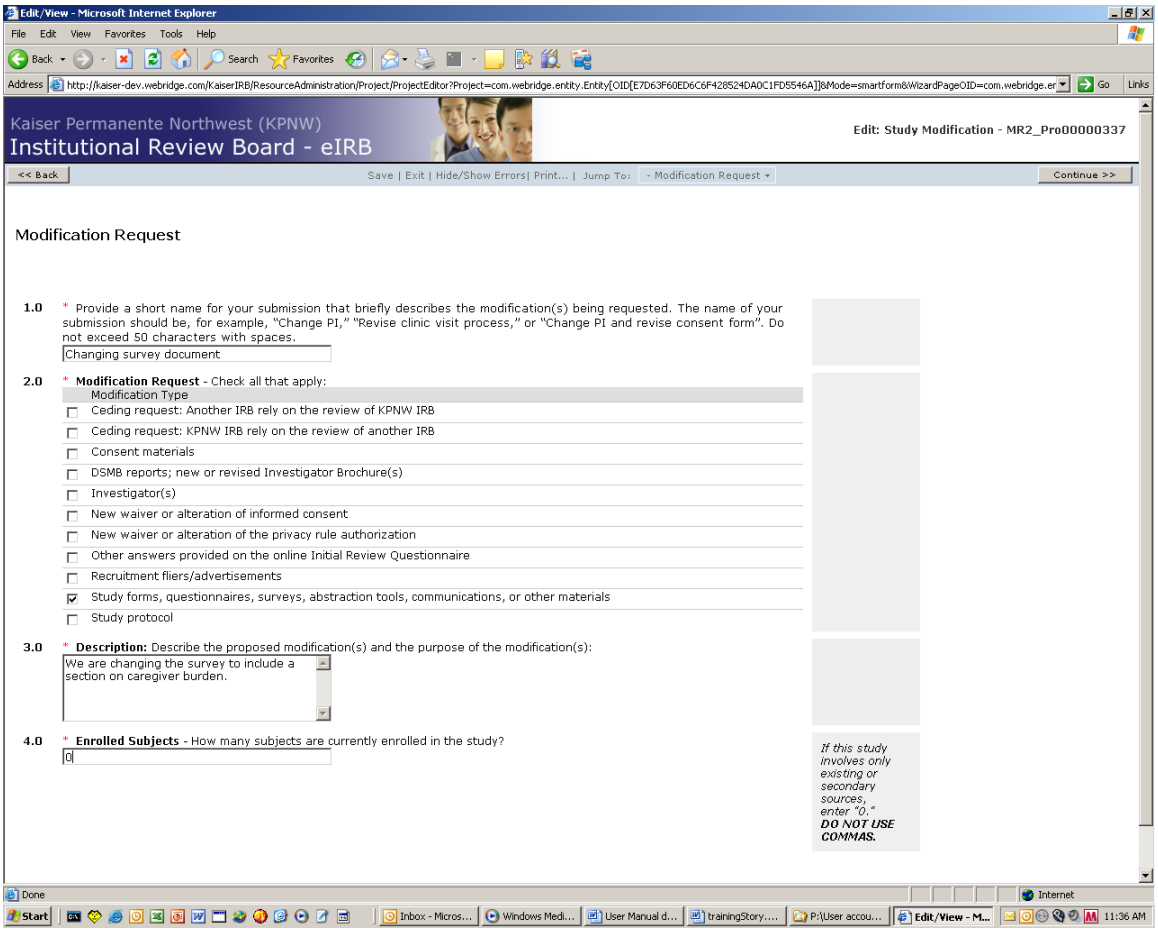


Figure 30

Once the first screen has been filled out, click on the 'Continue' button in order to answer all applicable questions.

If your modification includes changes to any of the following, you will use a *link* to make the desired modification(s) by directly editing/revising a copy of the currently approved IRQ (see Figure 31).

- Consent materials
- DSMB reports and/or new or revised Investigator Brochure(s)
- Investigator(s)
- New waiver or alteration of informed consent
- New waiver or alteration of the privacy rule authorization
- New or revised Risk Assessment and Mitigation Process (RAMP)
- Recruitment flyers/advertisements
- Study forms, questionnaires, surveys, abstraction tools, communications or other materials
- Study Protocol
- Other answers provided on the online Initial Review Questionnaire

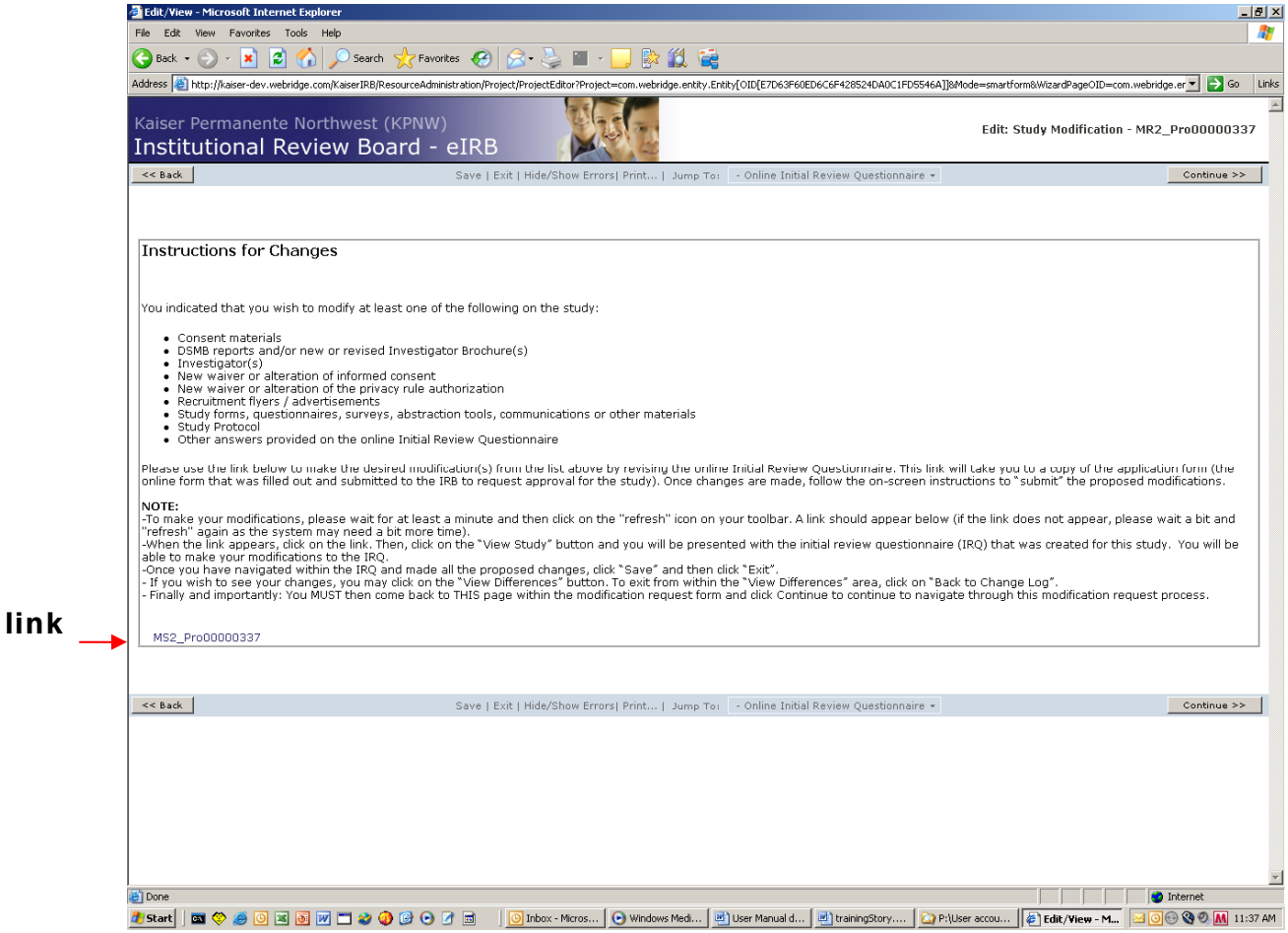


Figure 31

The link shown in Figure 29 should appear after you hit 'refresh' (as described in the instructions on screen); if the link does not appear, please wait a few minutes and then 'refresh', as the system may need a bit more time. The more documents in the IRQ, the longer it will take for the link to appear. Click on the link shown in Figure 31. This will take you to an area where you can click on the 'View Study' button (see Figure 32). This will navigate you in a new window or tab to a *copy of the approved IRQ* (i.e., the online form that was filled out and submitted to the IRB to request approval for the study), called the 'Modified Study'. You will be able to make your modifications directly onto this copy of the IRQ. A link to the Modified Study will also be available from the Modification workspace.

Use this same process to request to add documents and/or to edit/replace previously approved documents. To make the additions and/or the edits/replacements, navigate to the screen within the IRQ where such documents had been referred to/uploaded.

IMPORTANT NOTE ABOUT DOCUMENTS: It is important that you DO NOT DELETE any currently approved documents in the Modified Study, unless specifically instructed to do so by the RSPO staff. Use the 'Edit' button to upload revised documents, or add new documents.

Once you have navigated within the IRQ and made all the proposed changes, click 'Save' and then 'Exit'. Once the Study modification is complete and error-free, the PI should submit it for review using the 'submit activity' (see submission section above).

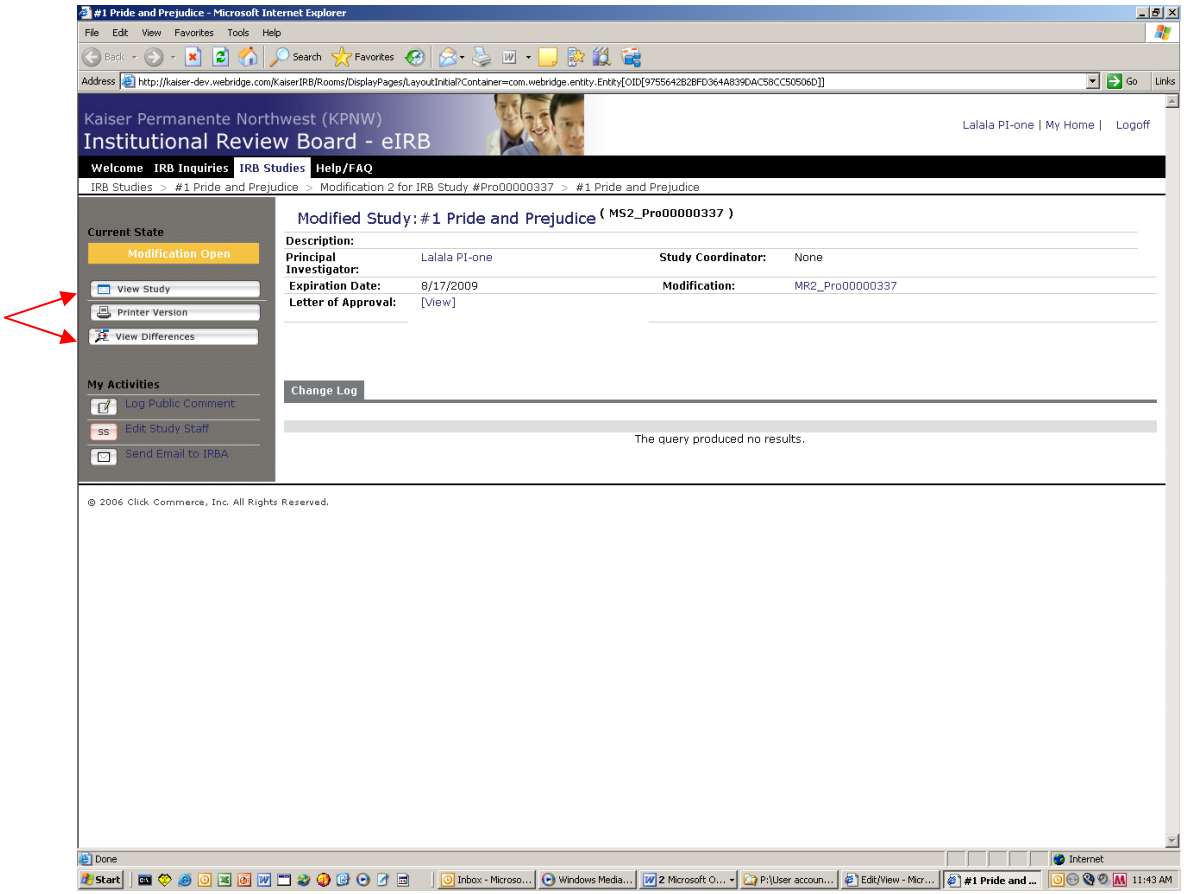


Figure 32

If you wish to see your requested changes to the IRQ compared to the approved version of the IRQ, you may click on the 'View Differences' button (see Figure 32). Then, to exit the 'View Differences' area, click on 'Back to Change Log'. Finally and importantly: You MUST then come back to the page within the modification request form (as shown in Figure 29) and click Continue to continue to navigate through this modification request. Then click 'finish' on the final screen. The PI will need to submit the modification request in the modification workspace.

Investigator changes

Investigator changes, including INTERIM changes, need to happen via the Modification Request form. If a PI needs to have a co-investigator do submissions in their absence, the PI needs to submit a Modification Request to switch the PI name, and then another submission needs to be done later by the 'interim PI' to 'switch it back'.

To make modifications to 'converted hardcopy' studies

Because you were allowed to enter an abbreviated form to convert your hardcopy study, to make modifications to these 'converted' studies, you may need to use the 'Other Study Information' page at the end of the IRQ which presents the following text-box labeled as follows: 'Optional: If you feel there is important/relevant information about this research that was not solicited previously, provide this information below:'. You can use this text box to write in information describing the proposed modifications.

You CAN do modifications/edits to documents (including adding new documents) on converted hardcopy studies since you were asked to upload documents with your conversion form. The documents you loaded are at the end of your IRQ. If you uploaded a protocol, you can also

submit proposed modifications by tracking changes on your protocol document and submitting that for review.

An important note about modification requests

You may only initiate one modification request at a time per study. Only one modification request can be 'submitted' (i.e., yet to be reviewed by the IRB) at a time. If you have already submitted a modification request to the IRB and realize you wish to request *another* modification *AND* if the modification request has *not* already been sent to a reviewer or discussed at an IRB meeting:

- You can contact the IRB (see Send Email to RSPO activity on the workspace) to ask if the already submitted modification request can be routed back to the investigator so that the investigator can insert/append the additional modification request(s) within the submission; *or*
- You may 'withdraw' the original modification request submission. This would then allow the PI to create and submit an entirely new modification request.

If the RSPO has determined that a modification must go to the full board, but it is urgent that a minor modification be approved through an expedited review, contact the RSPO staff, who can provide guidance on how to accommodate these requests.

CREATING REPORTABLE EVENT SUBMISSIONS

Reportable events are unanticipated events related to the research that involve increased risk to subjects.

In order to submit a Reportable Event, open your active study and click on the 'New Reportable Event' button located in the left portion of the screen (see Figure 33). You are able to submit and have more than one Reportable Event submission pending IRB review at a time.

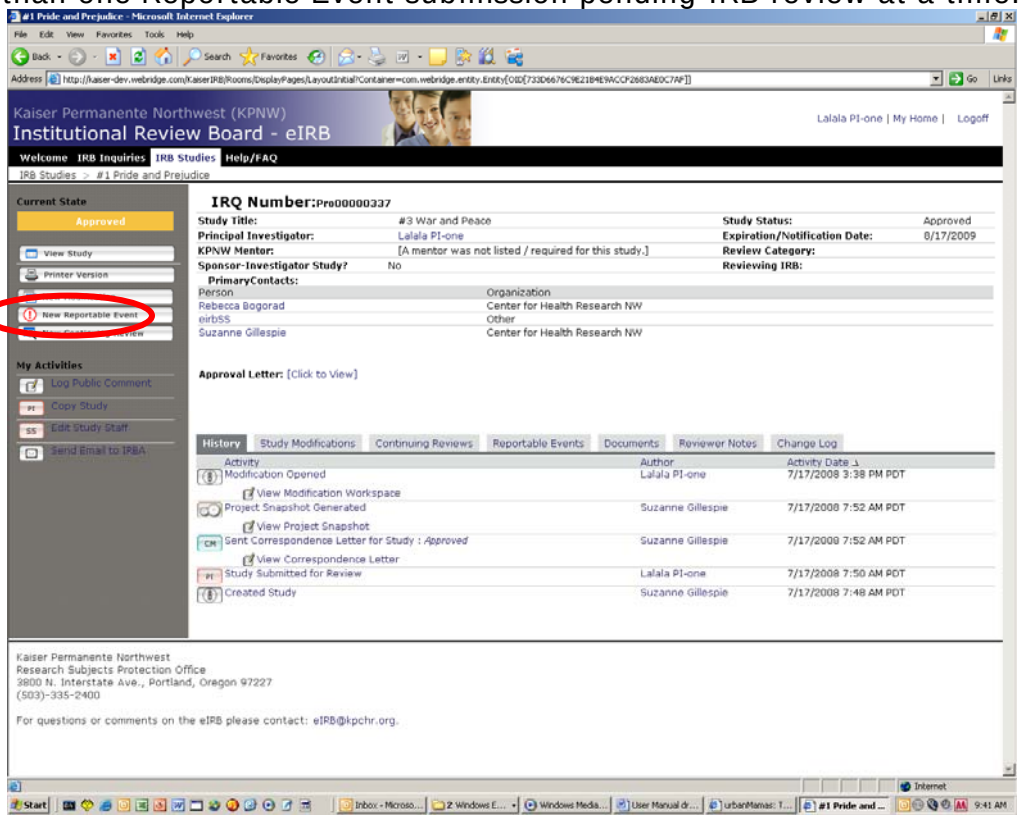


Figure 33

The Reportable Event form will open and prompt you to enter a short name for your submission. The name of the submission should be a short description of the event(s) being reported, for example, 'Participant hospitalization'. Do not exceed 50 characters with spaces (see Figure 34).

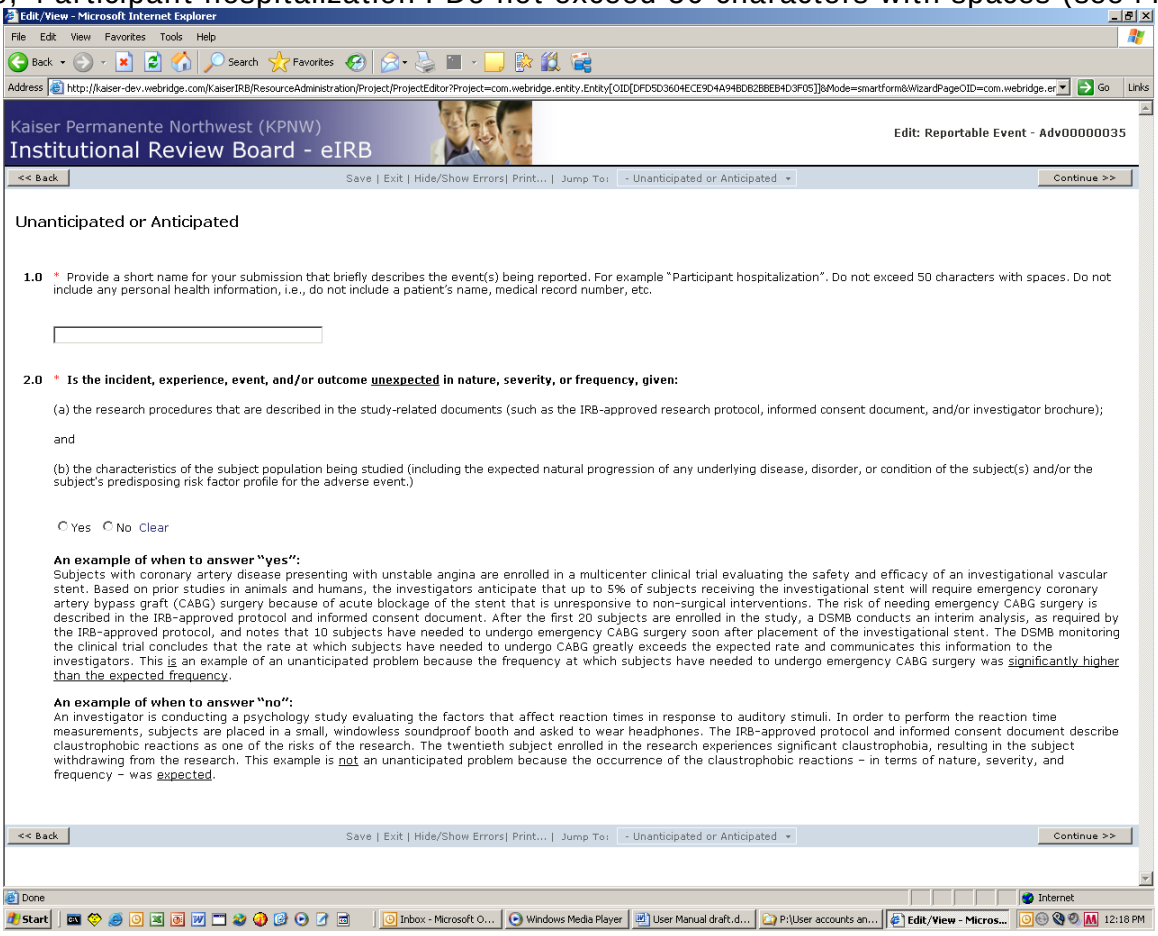


Figure 34

Answer the next question and click on the 'Continue' button in order to navigate through the questionnaire while answering all relevant questions. On the last page of the reportable event form, click 'finish' to complete the questionnaire. Once the form is complete and error-free the PI should submit it for review using the 'submit activity'.

You may discover that the event is NOT required to be reported to the IRB, or that it should only be reported in summary at the time of continuing review. The eIRB system will ascertain, through a series of questions, whether the event must be reported. You will be guided to submit, or to simply 'exit' and not submit and 'withdraw'.

Generally, studies will use this Reportable Event form to report problematic unanticipated incidents, experiences, events, and outcomes related to the study that have resulted in subjects or others experiencing physical, psychological, or other harms (such as social or economic harm) or that place subjects or others at increased risk of harm. In addition to this general rule, FDA-regulated studies with a KPNW sponsor-investigator (only) would *also* use this form to report any other additional incidents, experiences, events, and outcomes as were specifically stipulated and required by the KPNW IRB for the study.

CREATING IRB INQUIRIES

There is a new, optional submission type that was not available prior to the eIRB system. The form is designed for situations in which there is uncertainty about whether IRB review is necessary for a new project. This *optional* inquiry form would be submitted *prior* to a new study submission if you are unsure whether IRB review is required. When this form is submitted, it will be sent to a reviewer who will then indicate whether the new project will require IRB review.

In order to submit an inquiry form, from your home page click on the 'New IRB Inquiry' button located in the left portion of the screen (see Figure 35). This will bring up a short, one-page form (see Figure 36).

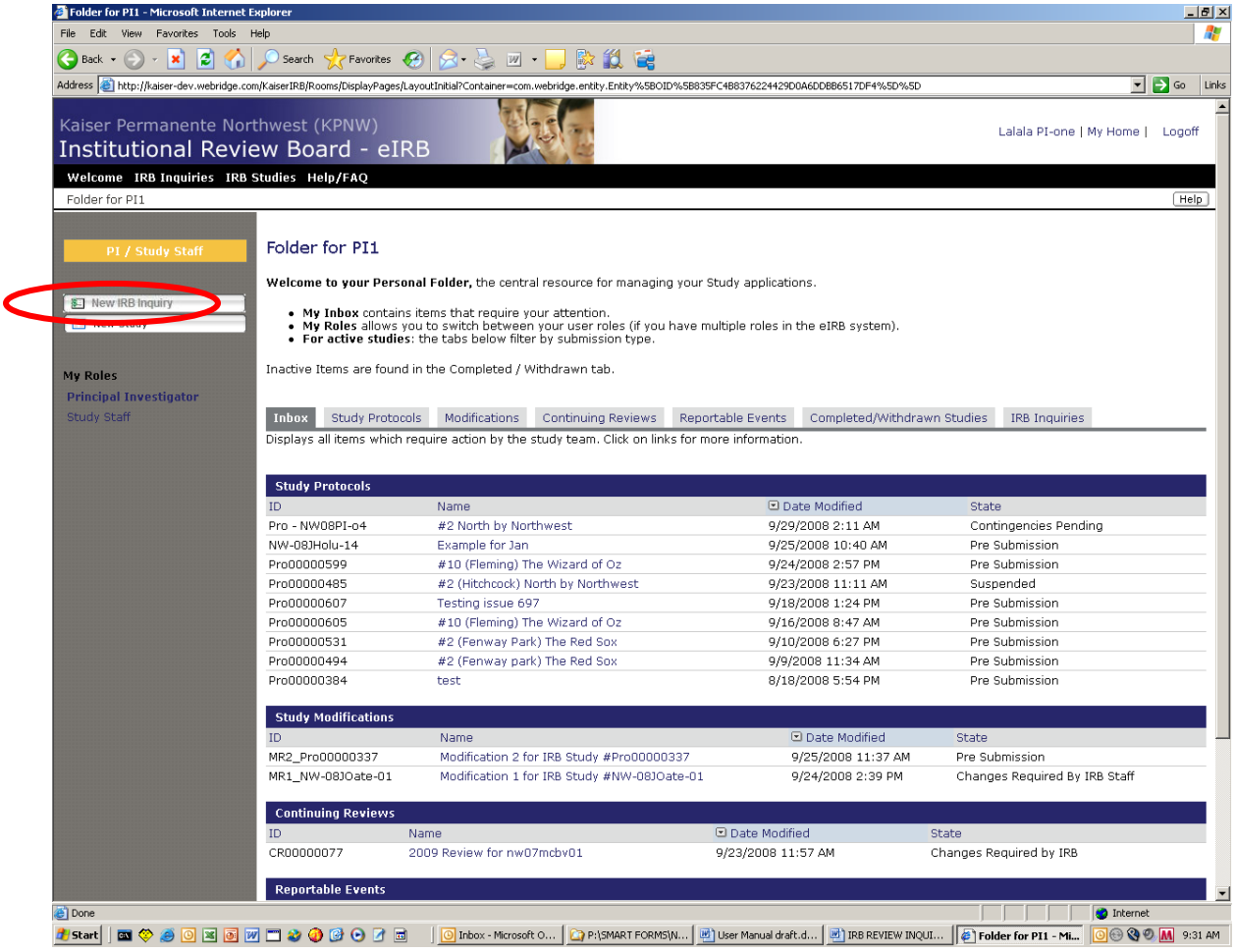


Figure 35

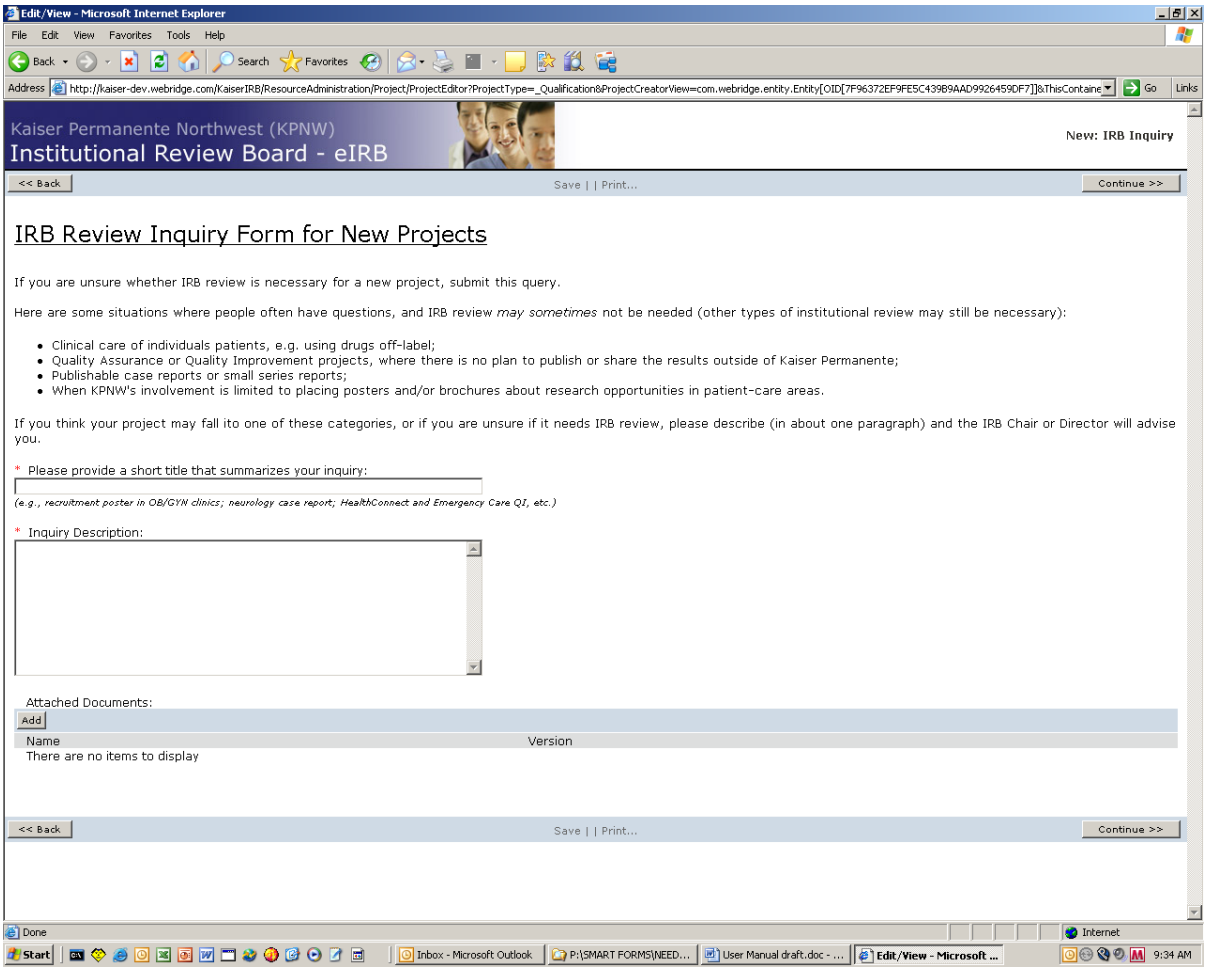

Edit/View - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://kaiser-dev.webridge.com/KaiserIRB/ResourceAdministration/Project/ProjectEditor?ProjectType=_Qualification&ProjectCreatorView=com.webridge.entity.Entity[OID[7F96372EF9FE5C439B9AAD9926459DF7]]&ThisContaine
Go Links
Kaiser Permanente Northwest (KPNW)
Institutional Review Board - eIRB
New: IRB Inquiry
<< Back
Save | | Print...
Continue >>
IRB Review Inquiry Form for New Projects
If you are unsure whether IRB review is necessary for a new project, submit this query.
Here are some situations where people often have questions, and IRB review may sometimes not be needed (other types of institutional review may still be necessary):
Clinical care of individuals patients, e.g. using drugs off-label;
Quality Assurance or Quality Improvement projects, where there is no plan to publish or share the results outside of Kaiser Permanente;
Publishable case reports or small series reports;
When KPNW's involvement is limited to placing posters and/or brochures about research opportunities in patient-care areas.
If you think your project may fall ito one of these categories, or if you are unsure if it needs IRB review, please describe (in about one paragraph) and the IRB Chair or Director will advise you.
* Please provide a short title that summarizes your inquiry:
(e.g., recruitment poster in OB/GYN clinics; neurology case report; HealthConnect and Emergency Care QI, etc.)
* Inquiry Description:
Attached Documents:
Add
Name
Version
There are no items to display
<< Back
Save | | Print...
Continue >>
Done
Internet
Start
Inbox - Microsoft Outlook
P:\SMART FORMS\NEED...
User Manual draft.doc - ...
Edit/View - Microsoft ...
9:34 AM

Figure 36

GLOSSARY: UNDERSTANDING 'ACTIVITIES'

(See Figure 24)

Accept Cede from other IRB – ALLOWS RSPO to indicate that the KPNW IRB accepts review responsibility for another IRB.

Acknowledge – ALLOWS RSPO to acknowledge receipt of reportable event submission.

Agree to mentor – ALLOWS the Mentor to attest to their mentoring responsibilities on the study, if a mentor is needed on the study.

Ceding revoked – ALLOWS the RSPO staff to revoke 'ceded status' on an active study, indicating that the KPNW IRB will assume review of the study.

Changes requested by contingency reviewer - ALLOWS the RSPO to forward a request for changes to the PI.

Changes Required by Expedited Reviewer – ALLOWS the RSPO to forward a request for changes to the PI.

Changes Required by IRB Staff – ALLOWS RSPO to submit a change request to the PI; the Principal Investigator will be notified that changes are required to the protocol.

Continuing review completed – ALLOWS RSPO to indicate that a continuing review is now complete. The study will therefore be in an 'approved' state.

Copy Study - This activity will COPY this study. The same Principal investigator will remain the Principal Investigator for the new Study.

Deny Cede from Other IRB - ALLOWS RSPO to indicate that the KPNW IRB does not accept review responsibility for another IRB.

Edit Consent Forms – Allows RSPO staff to modify the contents of the set of draft consent forms prior to project approval and document watermarking. Documents added to the draft consent form set via this activity will be available for watermarking using the Finalize Documents activity.

Edit Guest List – ALLOWS any member of the study team to edit (i.e., add, delete) the primary and secondary study staff/contacts on the project. (Does NOT allow either PI or co-investigator edits, which must be made through a modification request).

Edit letter- Allows RSPO staff to modify a letter that was previously sent to the study team (in the instance of an error or other need to revise).

Expedite approval – ALLOWS IRB Director to expedite approval of a submission.

Final Report Completed – ALLOWS the RSPO staff to indicate that a ceded study is closed.

Finalize Documents – ALLOWS RSPO staff to stamp and watermark multiple draft consent forms with the project approval and expiration dates. Once finalized, a copy of the corresponding document in the set of draft consent forms is converted to a read-only PDF, and is placed in the set of Approved Consent Forms for this project.

Issue Mentor Approval - ALLOWS the Mentor to approve a modification request submission.

Log Public Comment -ALLOWS any member of the study team or the IRB staff to log a comment in the project history log that is visible to everyone that has read access to the project. See Figure 37.

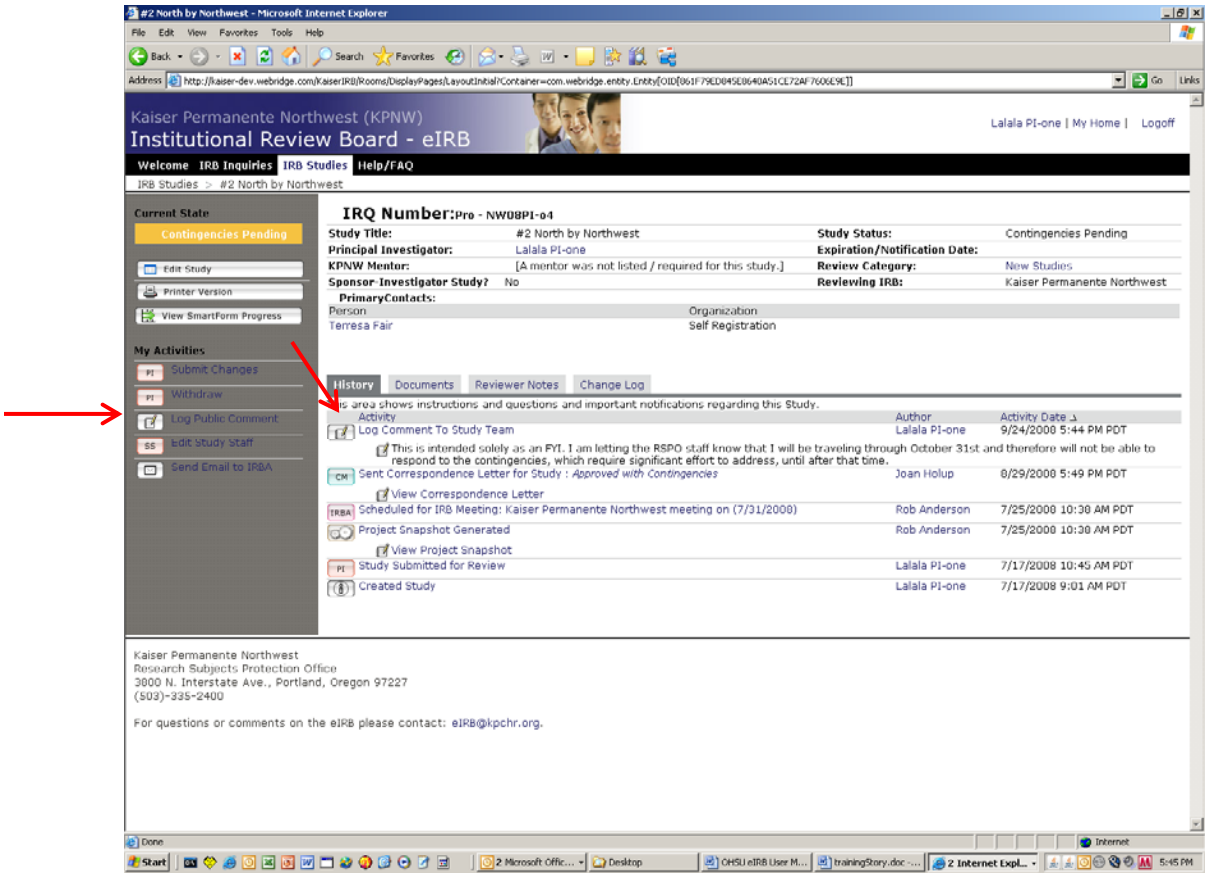


Figure 37

Other IRB accepts reliance and documents complete– ALLOWS the RSPO to indicate in the system that the other IRB has accepted review responsibility for the KPNW IRB. The study will be considered 'ceded' upon execution of this activity.

Other IRB denies request– ALLOWS the RSPO to indicate in the system that the other IRB does not accept review responsibility for the KPNW IRB. The submission reverts to 'pre-submission' status.

Reactivate – ALLOWS PI/SS to reactive the submission, which was previously 'withdrawn', so it can then be worked with/submitted.

Revoke Verification - ALLOWS the RSPO to indicate that a study previously verified as 'exempt' from IRB review now requires IRB review.

Schedule for IRB Meeting – ALLOWS RSPO to place the submission on a Board agenda and to assign a primary reviewer.

Send Correspondence to Study Team - ALLOWS correspondence manager to send IRB Correspondence to the study team.

Send email to IRBA - ALLOWS the study team to email the RSPO within the eIRB environment.

Study Completed – ALLOWS the study team to indicate that an exempt study is closed.

Submit – Once the submission draft is 'finished', 'Submit' ALLOWS the form to be submitted for IRB review. Reminder: The PI is the only person that can *submit*.

Submit Changes – ALLOWS the Principal Investigator to respond to a request for changes or clarifications from the IRB staff

Submit changes or contingency response – ALLOWS the PI to submit the requested changes or response to contingencies. Reminder: The PI is the only person that can *submit*.

Submit Continuing Review – Once the submission draft is 'finished', ALLOWS the PI to submit the form for IRB review. Reminder: The PI is the only person that can *submit* submissions.

Submit study – If you are the PI for a study, only you will have the option to submit (equivalent to a signature on paper) the study, continuing review, reportable event, or modification request. Once you have opened the submission draft and have reviewed it for accuracy, you may click on the 'Submit' activity located on the left section of the submission workspace page under My Activities. Once the submit action has been completed, the submission will enter the review process.

Suspend study– ALLOWS the PI or IRB to suspend a study; suspended studies must temporarily cease all study activities except those required to protect the health and welfare of study participants.

Terminate study– ALLOWS the PI or IRB to terminate a study, after which the study will no longer be in an 'IRB-approved' status.

Withdraw – ALLOWS the item to be withdrawn and archived. The 'Withdraw' action allows the PI to effectively cancel the submission. This action will be useful if, during the review process, events impact the plans for the study and it is decided that the study or particular submission will not proceed. Withdrawing the study will not delete the study and its information, but rather archive it. You will still be able to retrieve the information you have entered into the IRQ should the need arise in the future. See Figures 38 and 39.

To withdraw a study, click 'withdraw'.

This form will then pop-up so that you can indicate a general reason for withdrawing and include any comments.

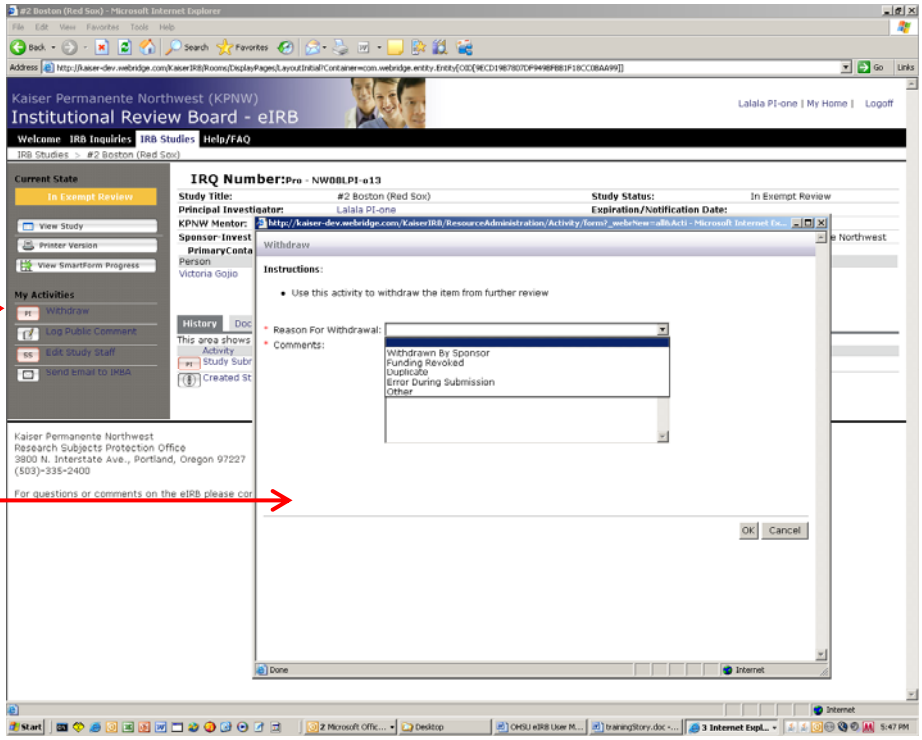


Figure 38

The study will then be in a 'withdrawn' state. If you wish to submit it later, you 'Reactivate' the submission, which will put it in a 'Pre-submission' state for you to revise, if needed, and then 'submit' again for review.

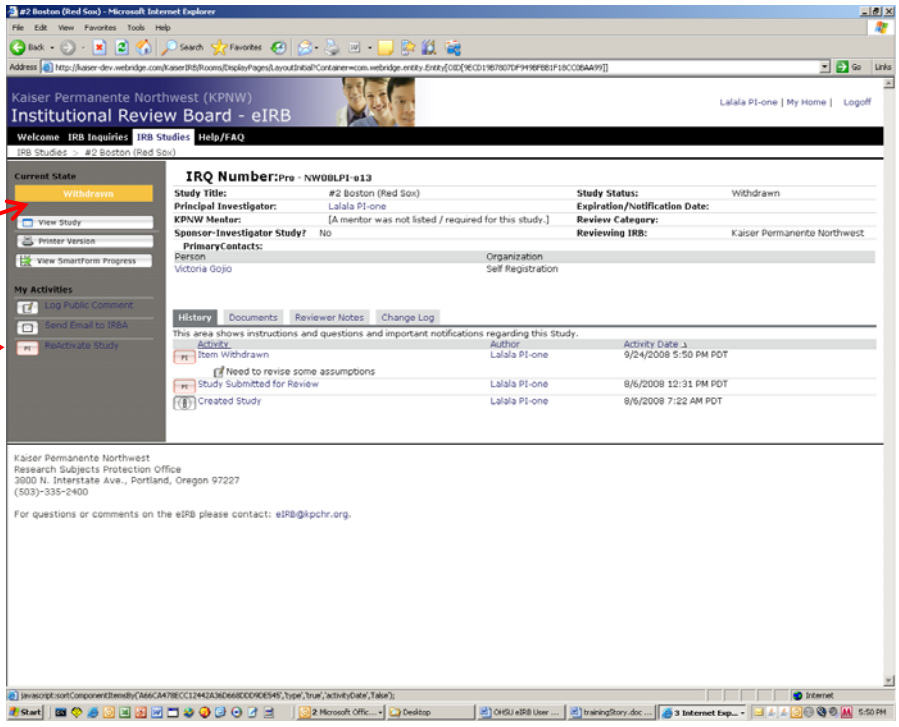


Figure 39

GLOSSARY: UNDERSTANDING 'CURRENT STATES'

(See Figure 24)

There are many different submission states. The following definitions (sorted in alphabetical order) provide a comprehensive explanation.

Acknowledged– The Reportable Event submission has been acknowledged.
Approved – The study, or submission, has been approved.
Assigned to IRB Meeting – The submission has been assigned to a KPNW IRB meeting.
Awaiting Correspondence - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.
Awaiting Other IRB Acceptance of Review - The ceding /reliance request submitted by the study team has been reviewed by the KPNW IRB. The KPNW IRB has contingently approved the request and is waiting for communication from the other IRB about whether they agree to accept the review responsibility.
Ceded to Other IRB - The ceding /reliance request submitted by the study team has been reviewed by the KPNW IRB. The KPNW IRB approved the request and the other IRB agreed to accept the review responsibility. The KPNW IRB is now relying on another IRB to conduct review of the study (it is 'ceded').
Changes Required by Exempt Reviewer - The submission has been forwarded to an exempt reviewer. The exempt reviewer has requested changes / clarifications from the PI.
Changes Required by Expedited Reviewer - The submission has been forwarded to an expedited reviewer. The expedited reviewer has requested changes / clarifications from the PI.
Changes Required by IRB – The IRB has reviewed the submission and has requested changes / clarifications from the PI.
Changes Required by IRB Staff – The IRB/RSPO staff have requested changes / clarifications from the PI.
Committee Member Review - The submission has been forwarded to a reviewer.
Changes Required by Committee Member Review (RE) - The Reportable Event submission has been forwarded to a reviewer. The reviewer has requested changes / clarifications from the PI.
Complete - The study is complete / closed/ no longer active.
Contingencies Pending - The IRB has reviewed the submission and has approved the submission 'with contingencies'. A response is now required from the PI in order for the submission to be formally approved.
Correspondence Review - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.
Designated Reviewer Contingency Review - The submission was reviewed and approved 'with contingencies'. The PI submitted a response, and this response is under review. (The PI response must be reviewed in order for the submission to be formally approved).
Disapproved– The study, or submission, was disapproved by the IRB.
Exempt Verified - The study was determined to be exempt from IRB review.
Expired - The study's IRB approval has expired.
In Exempt Review - The study has been forwarded to reviewer who will determine if the study is 'exempt' from IRB review.

In Expedited Review - The submission has been forwarded to a reviewer who will determine if the submission qualifies for expedited review.

In Expedited Review Contingencies Review - The submission was forwarded to a reviewer to determine if the submission qualifies for expedited review. The reviewer has requested changes/clarifications from the PI. A response is now required from the PI in order for the submission to be formally approved.

In Expedited Review Staff Review - The submission was forwarded to a reviewer to determine if the submission qualifies for expedited review. The submission is now with the RSPO.

IRB Correspondence Review - The submission has been reviewed. The RSPO is preparing related correspondence that will be sent to the study team.

IRB Qualification Review (inquiry) - The IRB Inquiry has been forwarded to a reviewer who will determine if the project will require IRB review.

IRB Staff Contingency Review - The submission was reviewed and approved 'with contingencies'. The submission is now with the RSPO.

IRB Staff Review - The submission is now with the RSPO to administratively handle.

Meeting Complete Awaiting Correspondence - The submission has been reviewed at an IRB meeting. The RSPO is preparing related correspondence that will be sent to the study team.

Not Engaged in Human Subjects Research – The IRB has determined that the submitted study does not require KPNWIRB review.

Pre Submission - The submission is being prepared by the study team.

Qualification Review Complete (inquiry) - The IRB Inquiry was reviewed and is complete.

Suspended - The study's IRB approval is 'suspended'.

Terminated – The study's IRB approval has been 'terminated'.

Withdrawn - The submission was withdrawn from the review process. It is no longer active within the review process.

GETTING HELP

eIRB Technical Support

You may receive technical assistance for the Kaiser Permanente Northwest (KPNW) eIRB system by contacting eIRB technical support at 503-528-3945 (tieline 60 3945) or at eIRB@kpchr.org during the following hours:

Monday - Friday ..... 9AM – 4:00PM

Training is strongly encouraged for new eIRB users.. Information regarding training can be found on the eIRB home page at http://eIRB.kpchr.org under Training Information and FAQ. You may also contact Lisa.M.LaForge@kpchr.org or at 503-335-6699 to request a training session.

Study (IRB) Related Support

For questions related to the wording and the meaning of the questions found within the eIRB, feel free to contact the Research Subjects Protections Office (RSPO) at (503) 335-6699 or at eIRB@kpchr.org.

You can also view the list of RSPO personnel and their contact information at http://www.kpchr.org/rspopublic/public/contactus.aspx?returnurl=/rspopublic/public/default.aspx&siteid=1.

Additionally, RSPO maintains a web site with useful information at http://www.kpchr.org/rspopublic/public/.

General Computer Help Desk

The General Computer Help Desk provided to the Center for Health Research/KPNW can be reached at 503-335-6671 (tie line 60-6671) or at hotline@kpchr.org for questions that are *not* related to the eIRB, such as questions relating to your operating system, network access, and common software applications installed on your computer.

Browser Requirements

Microsoft® Windows 9x, 2000, XP

- Microsoft® Internet Explorer 6.0 or higher available at http://www.microsoft.com/windows/ie/default.mspx

- Firefox 1.0 or higher on Windows platforms available at http://www.mozilla.com/en-US/products/firefox/

System Requirements

The eIRB system will function on Microsoft® Windows 95 and higher as long as the computer has Microsoft® Internet Explorer 6.0 or higher with cipher strength of 128 bit installed.

21 CFR Part 11 Compliance

The KPNW eIRB is compliant with 21 CFR Part 11, including electronic signatures. For more information, see the KPNW 21 CFR Part 11 Electronc Signature Compliance statement.

EXAMPLES OF COMMON ERROR MESSAGES

- You may experience the following error if the system is undergoing maintenance or service:

  'An internal server error occurred. We apologize for the inconvenience, and ask that you please try again later. If you continue to experience problems please contact the eIRB help desk at 503-528-3945 or eIRB@kpchr.org.'

- You may be presented with the following message if the eIRB system is *already* in the process of uploading a file into your submission and you attempt to upload a file again:

  'You have already submitted the current form. Please wait and the operation will be completed momentarily.'

- The following messages indicate that you have omitted to answer a required question on a screen:

  'Could not update the IRQ due to one or more errors:
  There were problems submitting this form...'

  This is a required field; therefore, you must provide a value.

- Example of error message generated if there is incongruous information entered, for example, if the numbered entered for 'total' study subjects is less than the numbered entered for study subjects 'specifically enrolled at the KPNW site':

  'Could not update the Continuing Review due to one or more errors:
  Validation Failed: The number entered for Newly Enrolled is greater than the Current Number of Participants/Subjects in the Study (at this site). You must revise your number(s).'

WHAT IS NOT FOUND IN THE E-IRB

- Single-patient use submission forms

- Emergency-use submission forms

If you need to make one of these types of submission to the KPNW IRB, please contact the RSPO for guidance.

V 1.02 1/2011